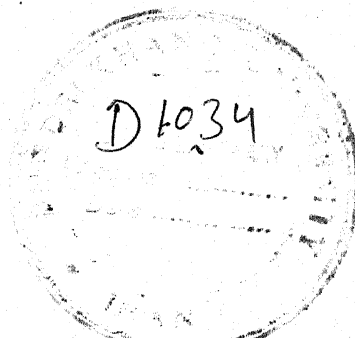


***A STUDY OF THE EFFECTS OF
RAW GARLIC AND GARLIC PEARLS
ON LIPID LIPOPROTEIN PROFILE IN
SUBJECTS OF HYPERCHOLESTEROLEMIA***

THESIS

FOR

**DOCTOR OF MEDICINE
(MEDICINE)**



**BUNDELKHAND UNIVERSITY
JHANSI (U.P.)**

2003

SHARAD CHANDUKA

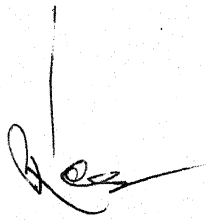
*Dedicated to
my
Grand Parents*

Certificate

This is to certify that the work entitled '*A study of the effects of raw garlic and garlic pearls on lipid lipoprotein profile in subjects of hypercholesterolemia*' has been carried out by Dr. **Sharad Chanduka** in the Department of Medicine, M.L.B. Medical College, Jhansi.

He has put in the necessary stay in the department as per University regulations.

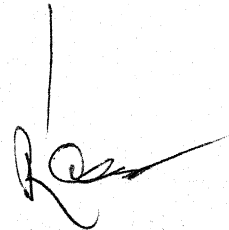
Dated :



(DR. R.C. ARORA)
M.D, D.Sc.
Professor & Head,
Department of Medicine,
M.L.B. Medical College,
Jhansi (U.P.)

Certificate

This is to certify that the work entitled '*A study of the effects of raw garlic and garlic pearls on lipid lipoprotein profile in subjects of hypercholesterolemia*' which is being submitted as a thesis for M.D. (Medicine) examination 2003. Bundelkhand University, has been carried out by **Dr. Sharad Chanduka** under my direct supervision and guidance. The techniques embodied in the thesis were undertaken by the candidate himself and the observations recorded were checked and verified by me from time to time

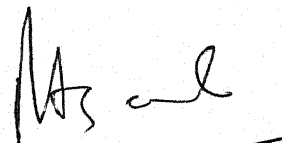


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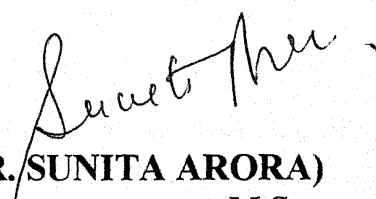
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This is to certify that the work entitled '*A study of the effects of raw garlic and garlic pearls on lipid lipoprotein profile in subjects of hypercholesterolemia*' which is being submitted as a thesis for M.D. (Medicine) examination 2003. Bundelkhand University, has been carried out by **Dr. Sharad Chanduka** under my direct supervision and guidance. The techniques embodied in the thesis were undertaken by the candidate himself and the observations recorded were checked and verified by me from time to time

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Finally I cannot forget to thank all the patients who were the subjects of my work and all those unnamed persons who were associated with this work.

Dated :

Sharad Chanduka
(SHARAD CHANDUKA)

CONTENTS

S.NO.	DESCRIPTION	PAGE NO.
1.	INTRODUCTION ...	1 - 5
2.	REVIEW OF LITERATURE ...	6 - 22
3.	AIMS AND OBJECTIVES ...	23
4.	MATERIAL AND METHOD ...	24 - 31
5.	OBSERVATIONS ...	32 - 60
6.	DISCUSSION ...	61 - 73
7.	SUMMARY & CONCLUSION ...	74
8.	BIBLIOGRAPHY ...	75 - 85
9.	MASTER CHARTS ...	86 - 100

Introduction

INTRODUCTION

Atherosclerosis is the leading cause of death and serious morbidity in the present human civilization. It is a progressive disease which begins in childhood and has manifestations in the middle to late adulthood.

Although any artery may be affected, the aorta, the coronary and the cerebral systems are the prime targets. Hence myocardial infarction, cerebral infarction and aortic aneurysms are the major consequences of this disease. Moreover, extensive atheromas are friable often yielding emboli of their grumous contents into the distal circulation (Atheroemboli) more commonly noted in the kidneys.

Other consequences of acutely or chronically diminished arterial perfusion are such as gangrene of the legs, mesenteric occlusion, chronic ischemic heart disease, ischemic encephelopathy and sudden cardiac death.

Hyperlipidemia, hypertension, cigarette smoking and diabetes are the most significant risk factors for atherosclerosis. The direct relationship between total serum cholesterol and the incidence of coronary artery disease (CAD) has been well established by Framingham study. Abnormalities in plasma lipoproteins and

dearrangements in lipid metabolism are the most firmly established and best understood risk factor for atherosclerosis.

Classically, risk factors involved in the causation of atherosclerosis are divided into two categories :

- i) Those modifiable by life style and/or pharmacotherapy.
- ii) Those that are essentially unmodifiable (eg. age, male gender, genetics).

Garlic (*Allium sativum* L.) has come to be seen as an all round treatment for preventing atherosclerosis the cause of heart disease and strokes.

Garlic also appears to slightly improve hypertension, protect against free radicals and slow blood coagulation. Garlic has also been proposed as a treatment for asthma, candida, colds and diabetes.

Garlic preparations have been found to slow hardening of the arteries in animals, reducing the size of plaque deposits by nearly 50%. It reduces serum cholesterol levels primarily by inhibiting cholesterol synthesis.

Both raw garlic and preparation of garlic act by similar mechanism which are related to the amount of garlic used and to

the mixture of multiple compounds from the sulfur containing class of thiosulfinates, ajoenes and dithins.

Five individual sulfur containing compounds in garlic are ajoene, methylajoene, allicin, 2-vinyl-4H-1,3 dithin and diallyldisulphide inhibit cholesterol synthesis by 37%-42%.

Garlic contains an essential oil allicin ($C_6H_{10}S_2O$) which contains allylpropyldisulphide, diallyldisulphide and several other sulfur compounds as mentioned above. It has also been found that garlic almost completely suppresses thromboxane B₂ synthesis.

Garlic inhibits platelet aggregation by alteration in both the platelet cyclooxygenase and lipooxygenase pathway. Work by Apitz Castro et al suggests that garlic inhibitory effect might be mediated through modification of the physiochemical properties of the plasma membrane, rather than by affecting the arachidonic or calcium metabolism of platelets.

Studies by Ariga et al have been shown that garlic extract which inhibit platelet aggregation by suppressing thromboxane synthesis is to be as methyl allyl trisulphide (MATS).

Garlic has also been found that it increases fibrinolytic activity. The precise mechanism(s) remain to be defined.

Many studies have found that certain forms of garlic can lower total cholesterol levels by about 9-12%²³. Although similar studies conducted at various parts of the world did not show any significant change in cholesterol levels by use of garlic^{1, 6, 26, 35, 36}.

Bordia et al²⁻⁴ have claimed that acute ingestion of garlic in healthy subjects will prevent fat induced changes in blood lipids, coagulation and fibrinolysis and they claimed it superior to clofibrate. Later Sainani et al⁵ confirmed the reported beneficial effects of garlic.

Henceforth promoters of essential oil extracts of garlic known as "Garlic pearls" (each capsule containing 0.625mg of garlic oil i.e. garlic oil 0.25%w/w excipients qs to 250mg) advertise their efficacy in reducing serum cholesterol and in preventing heart disease.

Although study conducted by Arora et al (1981)⁶ at department of Medicine, M.L.B. Medical College, Jhansi have demonstrated that garlic did not cause any significant change in serum cholesterol values and does not substantiate the efficacy of garlic in the management of IHD as a hypocholesterolemic or as a fibrinolytic agent.

Lipid lowering drugs such as statins are an exciting advance, they decrease hepatic cholesterol synthesis by inhibiting HMGCoA

reductase. They are highly effective in reducing total & LDL cholesterol, they usually increase HDL cholesterol. Long term efficacy and safety has been established.

A number of angiographic trials using statin monotherapy have been performed such as multicentre anti atheroma study (MAAS), multicenter coronary intervention study (CIS) that uniformly demonstrated significant improvement in the lipid profile with simvastatin plus diet therapy as compared with the changes induced by dietary intervention alone.

Scandinavian simvastatin survival study (4S) evaluated that simvastatin therapy resulted in a significant beneficial alteration of the lipid profile.

Therefore we, decided to re evaluate the effect of raw garlic and essential oil extracts of garlic on lipid lipoprotein profile in subjects of hypercholesterolemia and to compare the effect with that of the well known hypolipidemic drug simvastatin. The effect of withdrawal was also studied.

Review of Literature

REVIEW OF LITERATURE

Atherosclerosis is the leading cause of death and disability. It affects the various regions of the circulation and yields distinct clinical manifestations depending on the circulatory bed affected. Atherosclerosis is responsible for coronary artery disease, cerebrovascular disease, peripheral occlusive diseases and aortic aneurysm.

Atherosclerosis is a disease primarily of the elastic arteries preferentially large and medium sized muscular arteries. The basic lesion is the atheroma or fibrofatty plaque which consists of a raised focal plaque within the intima, having a core of lipid (mainly cholesterol and cholesterol esters) and a covering fibrous cap. (Robbins & Cotran, 1994). Various risk factors for atherosclerosis are present of them four are most significant i.e.

- Diet and hyperlipidemia (hypercholesterolemia, hypertriglyceridemia).
- Hypertension
- Cigarette smoking
- Diabetes

Others are obesity, physical inactivity, stress (type A personality), male gender, hyperhomocysteinemia etc.

Atherosclerotic plaques are rich in cholesterol and cholesterol esters which are mainly derived from the lipoproteins present in the blood.

Genetic disorders causing severe hypercholesterolemia manifests as premature atherosclerosis despite the absence of other risk factors eg. (congenital absence of LDL receptors).

Acquired diseases that cause hypercholesterolemia such as nephrotic syndrome and hypothyroidism increase the risk of IHD.

The Framingham heart study has elucidated the relation between total cholesterol, LDL-C, HDL-C, triglyceride levels and the risk for coronary atherosclerosis. During the 12 years follow up evaluation a total of 383 men and 227 women developed symptomatic CHD and showed a significant positive correlation with the categories of blood pressure, total cholesterol, LDL-C and HDL-C.

Framingham heart study also evaluated the association between the elevated plasma Lp(a) and CHD in a prospective manner¹³. Lp(a) was determined to be an independent risk factors comparable

to the attributable risk of total serum cholesterol in excess of 240mg/dl or an HDL-C level of less than 35mg/dl.

Cholesterol :

Cholesterol is an amphipathic lipid and as such is an essential structural component of membranes and of the outer layer of plasma lipoproteins. Lipoprotein transport free cholesterol in the circulation where it readily equilibrates with cholesterol in other lipoproteins and in membranes.

It is synthesized in many tissues from acetyl-CoA and is ultimately eliminated from the body in the bile as cholesterol or bile salts. Cholesterol is the precursor of corticosteroids, sex hormones, bile acids and vitamin D.

It occurs in foods of animal origin such as egg yolk meat, liver and brain and a major risk factor for atherosclerosis (Harper 1996).

Triglyceride :

Triglyceride is synthesized from phosphatidate which in turn is synthesized from acylation of glycerol 3 phosphate by enzyme glycerol 3 phosphate acyl transferase. These are the major energy storing lipids (Harper 1996). Some studies have shown that plasma triglycerides levels >130-150mg/dl are associated with low HDL cholesterol and small dense LDL particles. Meta analysis of several

prospective population studies confirms that triglyceride concentrations are independent risk predictor of coronary heart disease.

Lipoproteins :

Lipoproteins are spherical particles made up of hundreds of lipid and protein molecules. The major lipids of the lipoproteins are cholesterol, triglycerides and phospholipids. Triglycerides and cholesterol esters (esterified form of cholesterol) are hydrophobic and forms the core of the lipoprotein.

Phospholipids and a small quantity free (unesterified) cholesterol are amphipathic and cover the surface of the particle. According to the density lipoproteins of plasma have been grouped into four groups. As the proportion of lipid to protein in a lipoprotein increases, the density decreases. According to increase of density they are classified as follows :

Table No.1

Multiple studies have revealed that there is an inverse relationship between the HDL level and the risk of coronary events. HDL helps in reverse cholesterol transport from the tissue back to liver.

Table No : 1
Compositions of the lipoproteins in plasma of humans :

Fraction	Source	Density	Protein (%)	Total lipid (%)	Composition				
					Triacylglyceride	Phospho-Lipid	Cholesteryl ester	Cholesterol (Free)	Free Fatty acid
Chylomicrons	Intestine	<0.95	1-2	98-99	88	8	3	1	-
VLDL	Liver (Intestine)	0.95-1.006	7-10	90-93	56	20	15	8	1
IDL	VLDL	1.006-1.019	11	89	29	26	34	9	1
LDL	VLDL	1.019-1.063	21	79	13	28	48	10	1
HDL2	Liver &	1.063-1.125	33	67	16	43	31	10	-
HDL3	Intestine								
	VLDL, Chylomicrons	1.125-1.210	57	43	13	46	29	6	6
Albumin FFA	Adipose tissue	>1.281	99	1	0	0	0	0	100

VLDL – Very low density lipoprotein, LDL – Low density lipoprotein

IDL – Intermediate density lipoprotein, HDL – High density lipoprotein

Apolipoproteins :

The protein moiety of a lipoprotein is known as an apolipoprotein. The apolipoproteins (apos) provide structural stability to the lipoproteins and determine the metabolic fate of the particles upon which they reside.

Apolipoproteins of human plasma lipoproteins (Table No – 2)

Apolipoprotein	Lipoprotein	Metabolic Functions
Apo AI	HDL, Chylomicrons	Structural component of HDL, LCAT activator
Apo AII	HDL, Chylomicrons	Unknown
Apo IV	HDL, Chylomicrons	Unknown, possibly facilitates transfer of other apos between HDL and Chylomicrons
Apo B48	Chylomicrons	Necessary for assembly and secretion of chylomicrons from the small intestine
Apo B100	Chylomicrons, VLDL, IDL, LDL	Necessary for secretion of VLDL from liver, ligand for LDL receptor
Apo CI	Chylomicrons, VLDL, IDL, HDL	May inhibit hepatic uptake of chylomicron and VLDL remnants
Apo CII	Chylomicrons, VLDL, IDL, HDL	Activator –lipoprotein Lipase
Apo CIII	Chylomicrons, VLDL, IDL, HDL	Inhibitor of lipoprotein Lipase, may inhibit hepatic uptake of chylomicron and VLDL remnants
Apo E	Chylomicrons, VLDL, IDL, HDL	Ligand for binding lipoprotein to LDL receptor.

LCAT : Lecithin cholesterol acyl transferase.

According to the National Cholesterol Education Programme (NCEP) expert panel on detection, evaluation and treatment of high Blood Cholesterol in adults (Adult treatment Panel III). Major risk factors (exclusive of LDL cholesterol) for CHD are as follows:

- ♦ Cigarette smoking
- ♦ Hypertension (blood pressure $\geq 140/90$ mm of Hg or on antihypertensive medication).
- ♦ Family history of premature CHD (CHD in male first degree relative < 55 yrs; CHD in female first degree relative < 65 years).
- ♦ Age (men ≥ 45 years; women ≥ 55 years).

Diabetes is regarded as a coronary heart disease risk equivalent i.e. a condition that carries an absolute risk for developing new CHD equal to the risk for having recurrent CHD events in persons with established CHD.

Hence forth, hypercholesterolemia and hypertriglyceridemia are considered as directly and indirectly predisposing factors for ischemic heart disease and it is presumed that garlic may be beneficial in the primary or secondary prevention.

Garlic (Allium Sativum) :

Garlic (*Allium Sativum* family Liliaceae) is widely distributed and used in all parts of the world as spice and food. Garlic is a dietary supplement regarded simultaneously as a food and a medicinal herb and has been used as such from the times of Egyptians Pharoahs and the earliest of chinese dynasties.

More than 1000 papers have been published in the past 20 years on garlic and related alliums. Garlic was called "Russian penicillin" during world war II because garlic were used to prevent wound infections.

Garlic exhibits potentially beneficial clinical activity as an antihyperlipidemic, antimicrobial, antiplatelet, antioxidant, antidiabetic and as a vasoprotective agent. Extensive clinical and scientific studies partially support the use of garlic for the treatment of hypercholesterolemia, infection and the prevention of atherosclerosis. Garlic also appears to slightly improve hypertention, protect against free radicals and slow blood coagulation.

Regular use of garlic may prevent cancer although it has been stated that garlic raises immunity but no real evidence is present to support the view. It has also been proposed as a treatment for asthma, candida and colds.

Mechanism of action

Garlic is composed of many natural sulfur compounds including a sulfur containing amino acid alliin (S-allyl-L-cysteine sulfoxide). Alliin is pharmacologically inactive. When garlic is crushed, alliin mixes with the enzyme alliinase it is converted to allicin (diallyl thiosulfinate). Allicin is unstable and upon steam distillation or maceration yields various diallyl and dimethyl sulphides plus E-ajoene and Z-ajoene.

The total activity of garlic is in its ability to produce allicin, which then produces other active principles which is referred to as the allicin yield.

Hypocholesterolemic action :

Garlic and wild garlic reduces serum cholesterol levels primarily by inhibiting cholesterol synthesis. Allicin sulfhydryl binding ability explains its cholesterol lowering effect as sulfhydryl containing compounds are involved in the synthesis of cholesterol. Sulfide bridges are formed by the disulfides found in garlic with 3-hydroxy-3methyl glutaryl CoA (HMG-CoA) reductase or the molecules found in lipids. HMG-CoA reductase is the rate limiting step in the synthesis of cholesterol as it catalyzes the intermediate step i.e. the formation of mevalonate from acetyl -CoA. Therefore,

allicin is commonly accepted as the pharmacologically active component in garlic.

ANTIPLATELET ACTION

Makheja et al has shown that garlic extract inhibits platelet aggregation, by suppressing thromboxane β_2 synthesis. Garlic inhibits platelet aggregation by alteration in both the platelet cyclooxygenase and lipooxygenase pathway.

Ariga et al have isolated the component as methyl allyl trisulphite (MATS).

Apitz Castro et al suggested that garlic's inhibitory effect might be mediated through modification of the physiochemical properties of the plasma membrane, rather than affecting the arachidonic or calcium metabolism of platelets.

VASOPROTECTIVE EFFECT

Garlic's vasoprotective effect was demonstrated due to increased nitric oxide synthetase activity, which may facilitate endothelium dependent smooth muscle relaxation. Thus, garlic may improve aortic elasticity through restoration of impaired endothelium. Although other studies suggest that garlic also increases fibrinolytic activity.

In contrary to the common belief study conducted by Arora RC et al 1981 at Dept. of Medicine, M.L.B. Medical College, Jhansi showed that after 12 wks of intake of garlic, patients did not show any appreciable change in plasma fibrinogen levels or coagulation time.

HYPOGLYCEMIC ACTION

Garlic decreases blood glucose levels by increasing serum insulin and glycogen storage in liver.

The health benefits of garlic supplements remain a controversial topic. On one hand there appear to be quite a large number of studies indicating a beneficial cardiovascular effect of garlic supplements, on the other hand the most well controlled studies generally suggest a lack of any beneficial effect of garlic supplements.

(Bordia, et al 1974-75)²⁻⁴ have claimed that acute ingestion of garlic in healthy subjects will prevent fat induced changes of blood lipids, coagulation and fibrinolysis. Study was only of 10 cases and they were so impressed by the results that they proceeded to assess the effect of garlic on experimental atherosclerosis in cholesterol fed rabbits and found it superior to clofibrate.

Later (Sainani et al, 1979)⁵ study on 5 subjects confirmed the beneficial effects of garlic, as showed by Bordia et al. Moreover they concluded that garlic and onion would result in significantly lowered ($p < 0.0001$) levels of serum cholesterol, serum triglyceride and β -lipoprotein (LDL).

(Arora RC, Arora S et al, 1981)¹ evaluated the effect of essential oil extracts of garlic and onion in the doses recommended by these authors.

Twenty healthy males (age 26.4 ± 5.12 yrs, weight 56.7 ± 7.3 Kg) and 13 proven cases of IHD (age 43.8 ± 9.5 yrs, weight 64.9 ± 8.2 Kg) were randomly chosen from patients attending MLB Medical Medical College & Hospital, Jhansi. and were given fat rich diet, fat rich diet + clofibrate, fat rich diet + garlic, fat rich diet + onion. The fasting & post prandial values of serum cholesterol and β -lipoprotein thus obtained in different test conditions did not show any appreciably change. Henceforth the so called beneficial effects of garlic and onion were not seen.

(Arora RC, Arora S, Gupta RK et al, 1981)⁶ undertook another study where garlic was given (a) for long period and (b) without fat induced hyperlipemia.

This study comprised of 30 proven cases of IHD (Gr I, 26 males and 4 females, age 41.0 ± 3.7 yrs) and 20 healthy volunteers

(Gr II, 18 males and 2 females, age 24.0 ± 4.1 yrs). Subjects were given essential oil of garlic i.e. six garlic capsules (each capsule containing 0.625mg of garlic oil) in 3 equally divided doses at meals for a period of 12 weeks. The STC, STG, β -lipoprotein and plasma fibrinogen and coagulation time values showed marginal fluctuations with insignificant 'P' values.

(Lau et al, 1987)¹⁴ conducted a study on 15 hyperlipidemic subjects they were treated with Kyolic aqueous garlic extract 1000 (4ml) daily for 24 weeks and 12 subjects were kept as control. Garlic significantly lowered cholesterol levels by about 9%.

(Vorberg & Schneider et al, 1990)¹⁵ conducted a trial in Germany over a 40 hypercholesterolemic subjects and they were counselled to take Kwai Tablets 900mg/day for 16 weeks. Garlic extract significantly lowered blood cholesterol >12%. Explanation of the large effect in this study was that there was less heterogenicity between the participants. Secondly this study used the highest daily and cumulative dose of garlic. It was estimated that the Kwai trials tested the equivalent of approximately one half to one clove fresh garlic per day.

(Mader et al, 1990)¹⁶ conducted a study in Germany. A total of 261 patients at 30 medical centers were given kwai tables (dried garlic extract) 800mg/day or placebo over the course of 16 weeks,

patients in the treated group experienced a 12% drop in total cholesterol and a 17% decrease in triglyceride levels. Patients who were having initial cholesterol levels of 250-300 mg/dl achieved maximum benefit. This study is considered to be one of the best study.

In the same period of 1990, (Auer et al)¹⁷ studied 47 subjects with hypertension average starting blood pressure of 171/100. Over a period of 12 weeks, half were treated with 600mg of garlic powder daily standardized to 1.3% alliin, the other half was given placebo. Results showed statistically significant drop of 11% drop in systolic blood pressure and 13% in diastolic pressure.

Review article- A meta analysis effect of garlic on total serum cholesterol was published in Ann Intern. Med 1993 by Stephen Warschafsky, et al²³, showed that garlic in an amount approximating one half to one clove per day (600-900mg) has been shown to decrease total serum cholesterol by about 9%.

A meta analysis published in the Journal of the Royal College of Physician by (Silagy CS, Neil HAW, et al, 1994)²⁴ states that garlic supplements cause overall 12% reduction in total cholesterol over a placebo and it is evident after only 4 weeks, treatment and that this was likely to persist for as long as the study was continued.

(Leon A Simons, Balasubramaniam S et al, 1995)²⁶ conducted a trial over 30 subjects with mild to moderate hypercholesterolemia after a dietary restriction for 28 day, subjects took kwai® garlic powder tablets 300mg three times daily or matching placebo for 12 weeks, followed by 28 days washout, followed by a 12 weeks crossover on alternative preparation there was no significant differences in plasma cholesterol, LDL-C, HDL-C, plasma triglycerides, Lp(a) concentration or blood pressure. This study clearly states against the findings of the previous meta-analysis.

Neil HAW et al 1996 undertook a trial of 115 subjects for six months by a kwai® tablets 300mg three times daily and concluded that garlic is less effective for reducing serum cholesterol than suggested by his own meta analysis in 1994 and expected that previous reports may be a publication bias, overestimation of treatment effects in trials with inadequate concealment of treatment allocation.

Similarly (Berthold HK et al, 1998)³⁵ and (Isaacsohn JL et al, 1998)³⁶ showed that garlic oil preparation, garlic powder respectively had no influence on serum lipoprotein, cholesterol absorption or cholesterol synthesis.

(Koscielny J et al 1999)²⁸ a double blind placebo controlled study that followed 152 individuals for 4 years found that garlic significantly reduced the development of atherosclerosis.

Lipid lowering drugs such as statins are an exciting advance, they decrease hepatic cholesterol synthesis by inhibiting HMG-CoA reductase. They are highly effective in reducing serum total cholesterol, LDL-C and usually increase HDL cholesterol. Long term efficacy and safety of the drug has been established.

With the publication of the Landmark **Scandinavian Simvastatin survival study (4S)** in 1994, where 4444 patients were treated for an average of 5.4 years. Simvastatin became the first lipid lowering agent proven to reduce morbidity and mortality in patients with CHD, as well as safe in long use⁵⁰. It showed that simvastatin improved patients survival by 30 percent and was well tolerated with a frequency of adverse events similar to those of placebo. Study was further reinforced by an eight year follow up of (4S) patients showing survival and safety were both continued⁵¹.

Original 4S data have been reanalysed to demonstrate additional attributes of simvastatin in the secondary prevention of CHD.

- ♦ A reduction in the development of new or worsened angina pectoris by 26 percent⁵².

- ♦ In patients with clinical diabetes, a significant decrease (42 percent) in the risk of major coronary events⁵³.
- ♦ In patients with impaired fasting glucose, a significant decrease (55 percent) in the risk of coronary mortality, total mortality (43 percent) and of major coronary events (38 percent)⁵³.

Simvastatin therapy resulted in a significant beneficial alteration of the lipid profile.

Patients were randomly assigned to receive either Placebo or 20mg of simvastatin per day. In the simvastatin group, total cholesterol was reduced by 28 percent, which was accompanied by a reduction in LDL-C levels of 38 percent. Simvastatin therapy resulted in 15 percent decrease in patients who had initial triglycerides levels were within the prescribed range of trial. Patients with significant hypertriglyceridemia before randomization had been excluded. HDL-C was increased by 8 percent.

Cerebrovascular events and new carotid bruits were also significantly reduced by simvastatin therapy.

Aims & Objectives

AIMS AND OBJECTIVES

- 1] To analyse the effect of raw garlic and garlic pearls on lipid lipoprotein profile in subjects of hypercholesterolemia when used as a food additive.
- 2] To analyse the effect of simvastatin on lipid lipoprotein profile in subjects of hypercholesterolemia when used as a drug.
- 3] To compare the results obtained from each study groups with other similar studies.

Material & Method

MATERIAL AND METHOD

The case material for the present study comprised of 30 subjects, out of which 3 subjects did not turned up after basal (registration), therefore total of 27 subjects are taken into consideration

The study was conducted in the department of Medicine, M.L.B. Medical College & Hospital, Jhansi. These subjects were selected from the patients attending the hypertension clinic, diabetic clinic, cardiac clinic, patients admitted in I.C.C.U. and wards of department of Medicine.

The study comprised of subjects who were hypercholesterolemic ($>200\text{mg/dl}$) or were having high serum triglyceride level ($>200\text{mg/dl}$) or both.

All the selected subjects were divided into 3 groups. Group A, Group B and Group C. Detailed information regarding the study was furnished to them and after that proper consent was taken. A total of 27 subjects were studied, 9 subjects in each group.

Group A : This group comprised of 9 subjects of which 7 were having hypercholesterolemia ($>200\text{mg/dl}$), 2 were having hypercholesterolemia as well as high serum triglyceride levels ($>200\text{mg/dl}$). This group comprised of 4 males and 5 females, age

50.5±10.6 years. Subjects under this group were counselled to take one clove of raw garlic per day for a period of 12 weeks with meal.

Group B : This group comprised of 9 subjects of which 6 were having hypercholesterolemia (>200mg/dl), 2 were having high serum triglyceride levels (>200mg/dl) and 1 was having both hypercholesterolemia and high serum triglyceride levels. This group comprised of 8 males and 1 female, age 49.7±9.8 years. Subjects under this group were counselled to take 4 garlic pearls (each capsule containing 0.625mg of garlic oil i.e. garlic oil 0.25%w/w excipients qs to 250mg) manufactured in India by Ranbaxy Laboratories Limited in 2 equally divided doses at meals for a period of 12 weeks.

Group C : This group comprised of 9 subjects of which 4 were having hypercholesterolemia and 5 were having both hypercholesterolemia and high serum triglyceride levels. This group comprised of 7 males and 2 females, age 48.3±10.4 years. Subjects under this group were counselled to take 20mg of simvastatin per day before evening meal for a period of 12 weeks.

METHOD

Subjects were allowed to eat their usual diet and to lead their routine life. Subjects were advised to either reduce or to stop smoking. Similarly they were advised to either moderate or not to

use alcohol during this period. Drug compliance are assured by asking them on every visit about their drug intake.

Detailed history regarding the diseases and drug intake was taken which is followed by physical examination and routine investigation.

DESIGN OF TEST :

All the selected subjects of each groups were asked to have dinner on the previous evening and after an overnight fast of 12 hrs, fasting blood samples were collected and were instructed not to take anything except water during that period.

Five fasting samples of blood were collected from each subjects for lipid and lipoprotein analysis throughout the study.

One each at registration (Basal) any day during 4th week, 12th week while using raw garlic, garlic pearls and simvastatin in respective group.

Two samples out of five, were taken at 1st and 3rd month of the withdrawal of raw garlic, garlic pearls and simvastatin.

Serum was separated from blood within half an hour by centrifuging, and on the supernatant of the samples the following tests were done.

1. Serum total cholesterol (STC) estimation was done by enzymatic procedure of Allain and Koeschlau using cholesterol esterase, cholesterol oxidase and peroxidase in a single reagent.

Estimation was done by one step method utilizing the kit provided by "Monozyme India Limited".

Procedure :

Three test tubes were taken and labelled as test(Tc), standard (s) and Blank (b) and then following steps were undertaken.

	Test (Tc)	Standard (s)	Blank (b)
Enzyme reagent (1)	1.0ml	1.0ml	1.0ml
Cholesterol standard (3) (200mg%)		0.01ml (10 μ l)	
Serum	0.01ml (10 μ l)		
Distilled water	0.1ml	0.1ml	0.1ml

Contents of all the tubes were mixed well and then incubated at room temperature for 10 minutes.

Optical density (O.D.) of each solution was measured against blank at 505nm (range 500-540nm). By blank calorimeter was set at zero and then calculation was done as follows:

$$\text{Total cholesterol/concentration of test sample (mg/dl)} = \frac{\text{O.D. of Tc}}{\text{O.D. of S}} \times 200$$

(Cholesterol 1mmol/L= 38.76mg/dl)

(Normal expected values <200 mg/dl)

2. Serum triglycerides (STG): It was estimated by enzymatic procedure of Bucolo and David modified by Trinder to a calorimetric test.

It was estimated by using GPO/POD method with ESPAS (N-Ethyl-N-Sulfopropyl-N-anisidine) utilizing the kit provided by 'Monozyme India Limited'.

Procedure:

Three test tubes were taken and labelled as test (T), standard (s) and blank (b) and then following steps were undertaken:

	Test (T)	Standard (s)	Blank (b)
Enzyme reagent (1)	1.0ml	1.0ml	1.0ml
Triglyceride standard (200mg%)		0.01ml (10µl)	
Serum	0.01ml (10µl)		

Contents of all the tubes were mixed well and then incubated at room temperature for 15 minutes.

Optical density (O.D.) of each solution was measured against blank at 546nm (range 540-560). By blank calorimeter was set at zero and then calculation were done as follows.

$$\text{Serum triglyceride (mg/dl)} = \frac{\text{O.D. of T}}{\text{O.D. of S}} \times 200$$

(or conversion in mmol/l = mg/dl \times 0.0114 mg/dl)

(normal expected value <150mg/dl)

3. High density lipoprotein cholesterol (HDL-c) was estimated by precipitating non HDL-c using phosphotungstic acid and magnesium ions. After precipitation, serum was centrifuged and HDL-c was estimated in the supernatant by enzymatic method using cholesterol esterase, cholesterol oxidase, peroxidase, 4-amino antipyrine and phenol.

Estimation of HDL-c was carried out in two steps. By the kit provided by 'Monozyme India Limited'.

(a) 1st step

In a centrifuge tube following substances were taken :

Serum	0.2ml
-------	-------

Precipitating reagent (2)	0.3ml
---------------------------	-------

Contents were mixed well and were kept at room temperature for 5 minutes following which it was centrifuged at 3000rpm for 10 minutes to get a clear supernatant.

(b) 2nd step

Same procedure as for the total cholesterol estimation as described above was followed, only the test sample was changed.

	Test (TH)	Standard (s)	Blank (b)
Enzyme reagent (1)	1.0ml	1.0ml	1.0ml
Cholesterol standard (3) (200mg%)		0.01ml (10μl)	
Supernatant (from step1)	0.1ml (10μl)		
Distilled water		0.1ml	0.1ml

Similarly as for the total cholesterol the tubes were incubated and the optical density was measured.

Calculation was done as follows:

$$\text{HDL cholesterol (mg/dl)} = \frac{\text{O.D. of TH}}{\text{O.D. of S}} \times 50$$

(normal expected value >40mg/dl)

4. Low density lipoprotein cholesterol and very low density lipoprotein (LDL and VLDL). VLDL-c and LDL-c were calculated by the following formula given by Friedelwald et al (1972) and Fredrickson DS (1972) respectively.

VLDL-c (mg/dl) = STG/5 (this formula is valid
if STG value is <600mg/dl)

LDL-c (mg/dl) = STC - (STG/5+HDL-c)
STC - (VLDL-c+HDL-c)

Analysis :

Results obtained were analysed statistically by student's t-test (Paired t-test).

Results were compared with each group and then conclusion was drawn.

Values of STC, LDL, HDL and Triglyceride are considered as normal or abnormal according to Adult Treatment Panel-III (ATP-III)

Total Cholesterol (mg/dl)	
<200	Desirable
200-239	Borderline high
>240	High
LDL Cholesterol (mg/dl)	
<100	Optimal
100-129	Near or above optimal
130-159	Borderline
159-190	High
>190	Very high
HDL cholesterol (mg/dl)	
<40	Low
>60	High
Triglyceride (mg/dl)	
<150	Normal
150-199	Borderline high
200-499	High
>500	Very high

Observation

OBSERVATION

The present study included 27 subjects which were divided into 3 groups. Each group comprised of 9 subjects.

Study comprised of subjects who were hypercholesterolemic ($>200\text{mg/dl}$) or were having high serum triglyceride levels ($>200\text{mg/dl}$) or both.

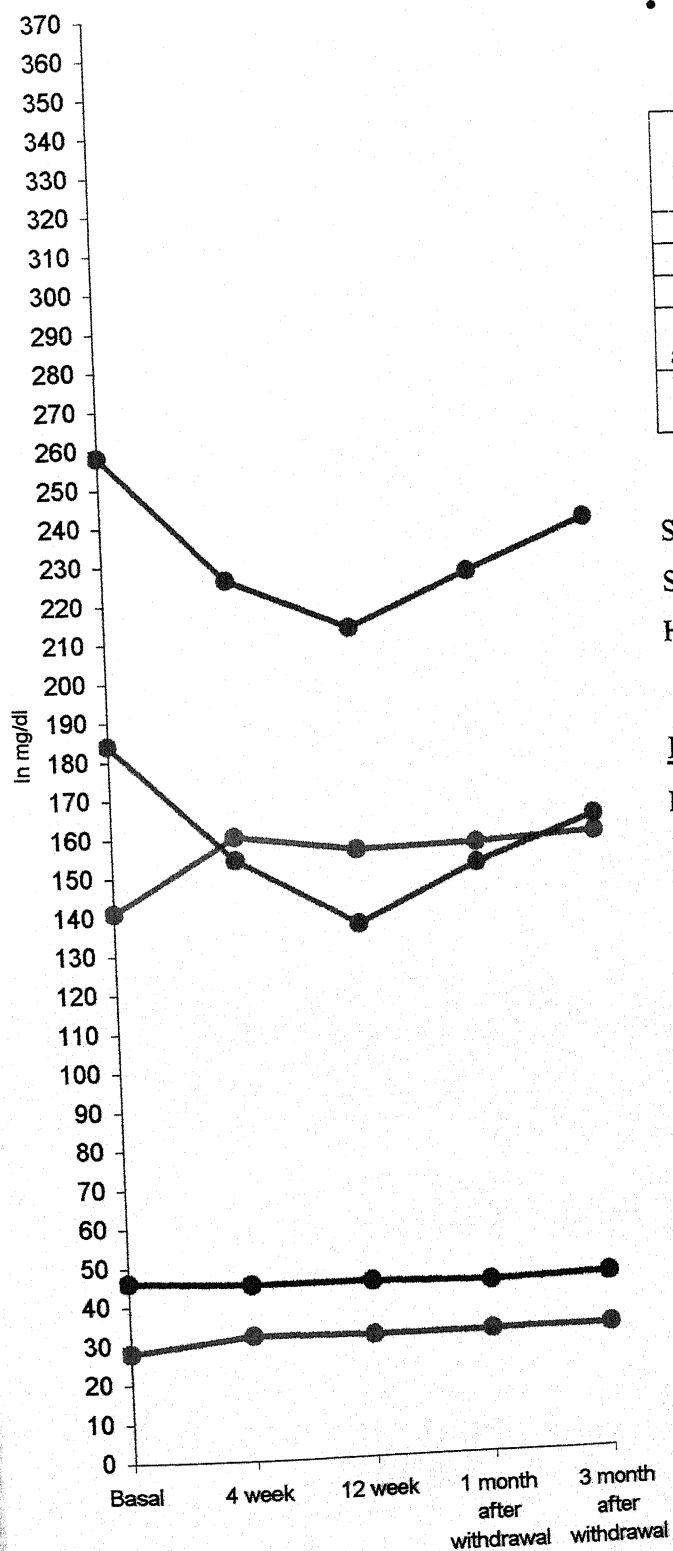
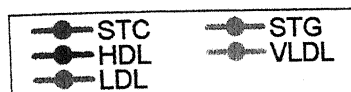
Subjects of group A were counselled to take one clove of raw garlic. Subjects of group B were counselled to take 4 garlic pearls and of group C were counselled to take simvastatin 20mg per day respectively. The care was taken not to consider the individuals who had taken drug other than specified to particular group with any effect on serum lipid lipoprotein profile.

All these were considered to note the response of raw garlic, garlic pearls and simvastatin on the lipid lipoprotein profile i.e. the levels of serum total cholesterol (STC), serum triglyceride (STG), serum high density lipoprotein (HDL), serum low density lipoprotein (LDL) and LDL/HDL ratio.

Abbreviations used in the tables are :

STC	Serum total cholesterol
STG	Serum triglyceride
HDL	Serum high density lipoprotein
VLDL	Serum very low density lipoprotein
LDL	Serum low density lipoprotein
LDL/HDL	Ratio of low density lipoprotein to high density lipoprotein
M/F	Male/female
MI	Myocardial infarction
With*	Withdrawal
AV Block	Atrioventricular block
NIDDM	Non insulin dependent diabetes mellitus
RBBB	Right Bundle branch block
TB	Tuberculosis
CAD	coronary artery disease

RAW GARLIC GROUP



- Puttan, 40 years/M
- Anterior wall MI with sinus arrest
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	258	141	46	28	184	4.0:1
4 week	226	160	45	32	154	3.4:1
12 week	213	156	45	31.2	136.8	3.0:1
1 month after with	227	157	44	31.4	151.6	3.4:1
3 month after with	240	159	45	31.8	163.2	3.6:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment -

12.4% \downarrow (STC), 13.5% \uparrow (STG),

2.1% \downarrow (HDL), 16.3% \downarrow (LDL)

After 12 weeks of treatment -

17.4% \downarrow (STC), 10.6% \uparrow (STG),

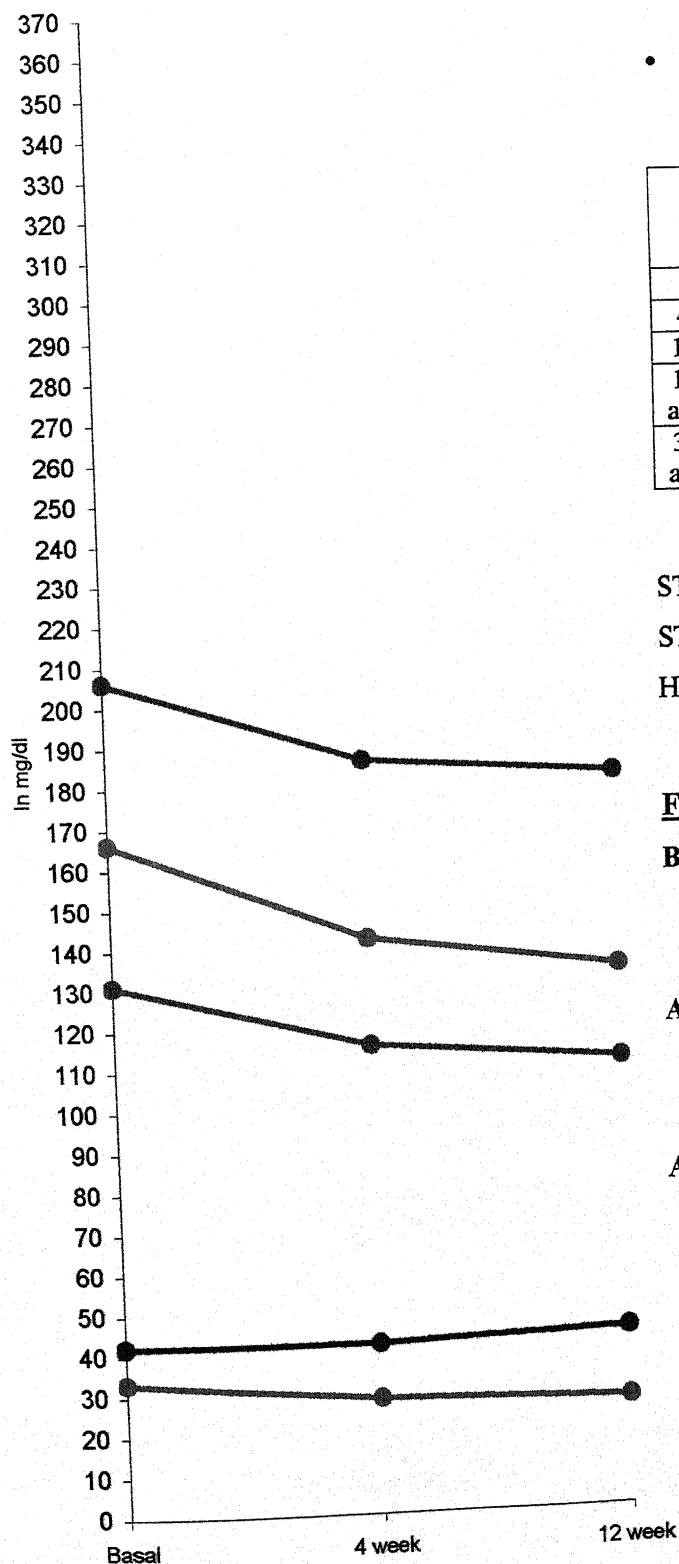
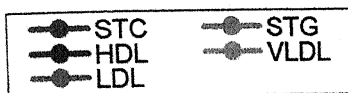
2.1% \downarrow (HDL), 25.6% \downarrow (LDL)

After 3 months of withdrawal -

7.5% \downarrow (STC), 12.7% \uparrow (STG),

2.1% \downarrow (HDL), 11.3% \downarrow (LDL)

RAW GARLIC GROUP



- Premdubey, 46 years/F
- Systemic hypertension with 1st degree AV block
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	206	166	42	33	131	3.1:1
4 week	186	142	42	28.4	115.6	2.8:1
12 week	182	134	44	26.8	111.2	2.5:1
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, Normal STG,
Normal HDL and High LDL

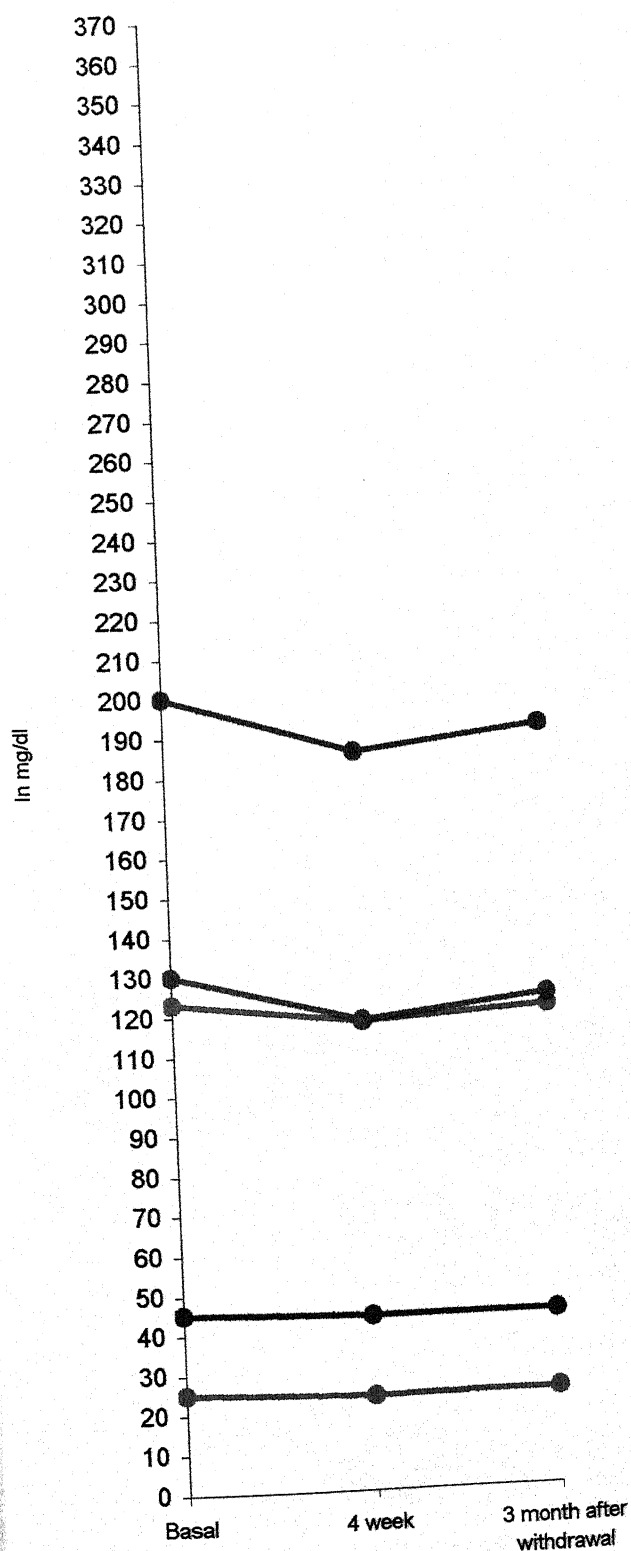
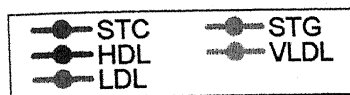
After 4 weeks of treatment -

9.7% \downarrow (STC), 14.45% \downarrow (STG),
No change in HDL, 11.7% \downarrow (LDL)

After 12 weeks of treatment -

11.6% \downarrow (STC), 19.3% \downarrow (STG),
4.8% \uparrow (HDL), 15.1% \downarrow (LDL)

RAW GARLIC GROUP



- Ragvendra Sharma, 68 years/M
- Acute Anterior wall MI
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	200	123	45	25	130	2.9:1
4 week	186	118	44	23.6	118.4	2.7:1
12 week	-	-	-	-	-	-
1 month after with	-	-	-	-	-	-
3 month after with	192	121	44	24.2	123.8	2.86:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,
Normal HDL and High LDL

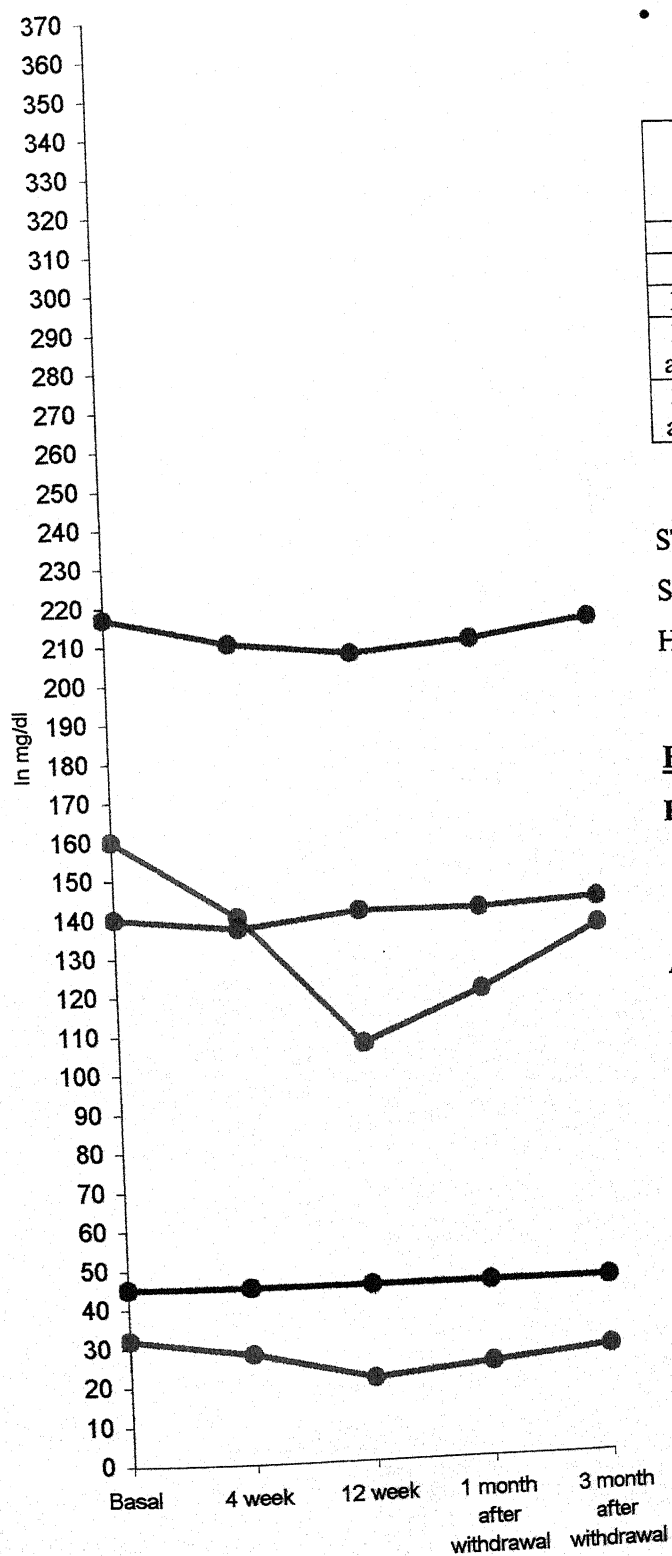
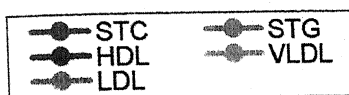
After 4 weeks of treatment –

7% \downarrow (STC), 4.06% \downarrow (STG),
2.2% \downarrow (HDL), 8.9% \downarrow (LDL)

After 3 months of withdrawal –

4% \downarrow (STC), 1.6% \downarrow (STG),
2.2% \downarrow (HDL), 4.8% \downarrow (LDL)

RAW GARLIC GROUP



- Madan Mohan Soni, 41 years/M
- Diabetes Mellitus
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	217	160	45	32	140	3.1:1
4 week	210	140	45	28	137	3.0:1
12 week	207	107	45	21	141	3.1:1
1 month after with*	210	120	45	24	141	3.1:1
3 month after with*	215	136	45	27.2	142.8	3.1:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment –

3.2% \downarrow (STC), 12.5% \downarrow (STG),

No change in HDL, 2.1% \downarrow (LDL)

After 12 weeks of treatment –

4.6% \downarrow (STC), 33.12% \downarrow (STG),

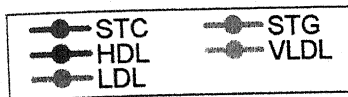
No change in HDL, 0.7% \uparrow (LDL)

After 3 months of withdrawal –

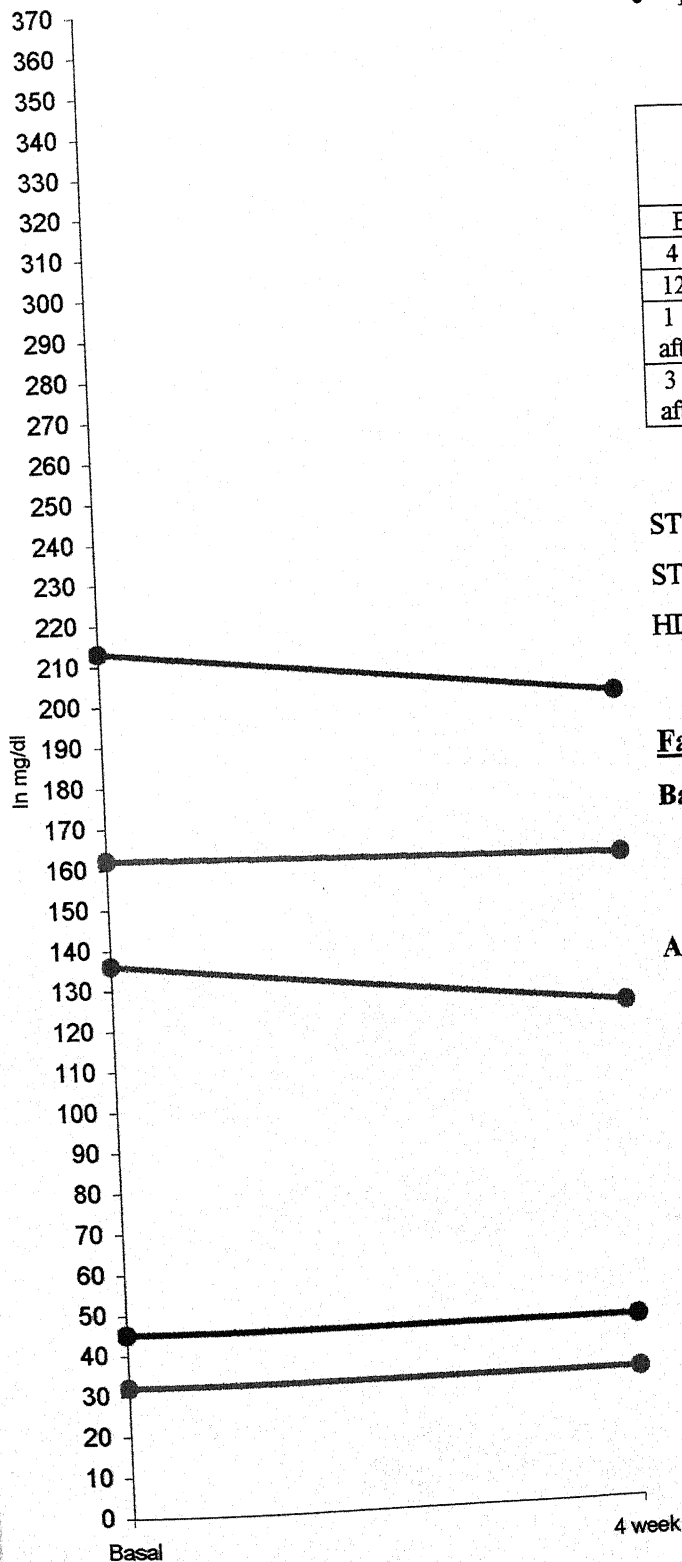
0.92% \downarrow (STC), 15% \downarrow (STG),

No change in HDL, 2% \uparrow (LDL)

RAW GARLIC GROUP



- Raja Bai, 52 years/F
- Systemic hypertension
- Hypercholesterolemia



	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	213	162	45	32	136	3:1
4 week	200	160	45	32	123	2.7:1
12 week	-	-	-	-	-	-
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

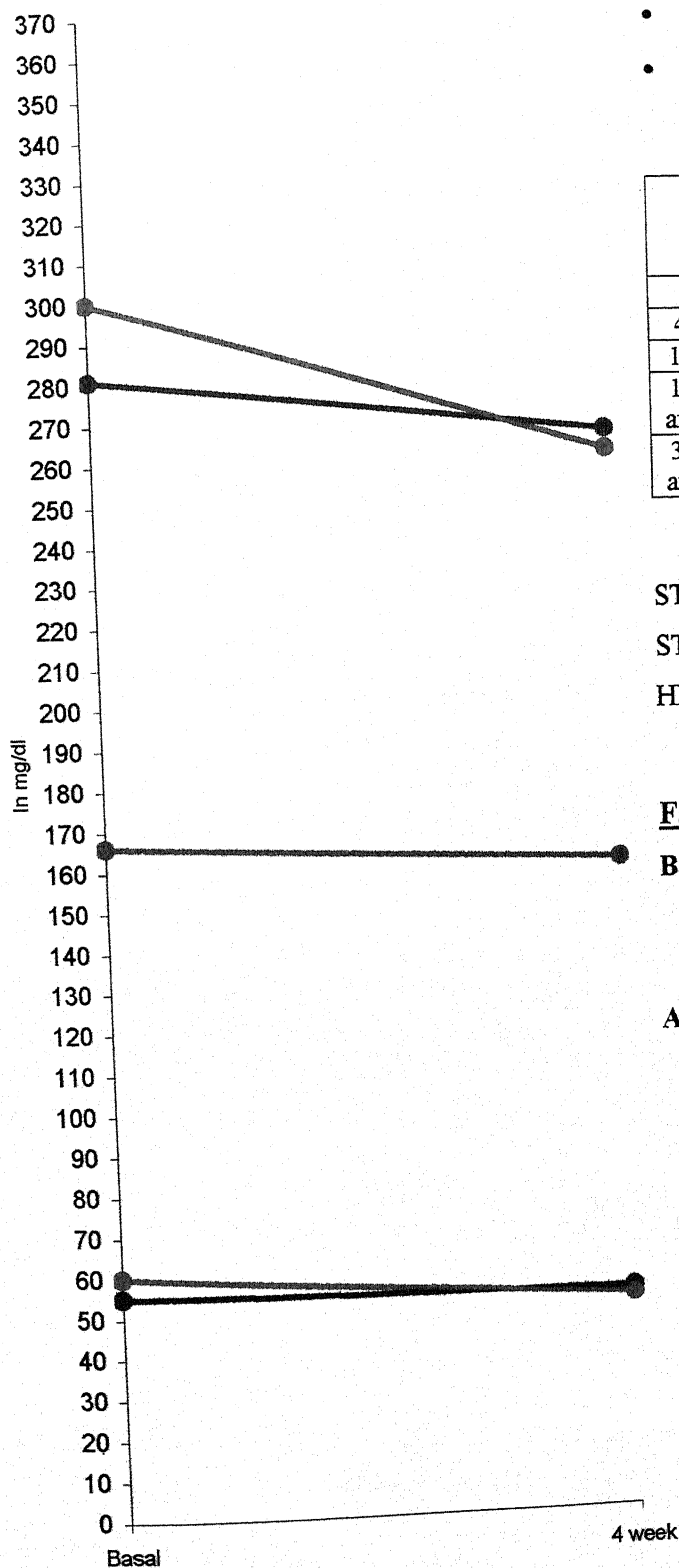
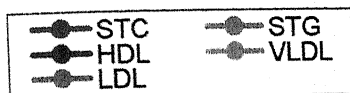
Normal HDL and High LDL

After 4 weeks of treatment –

6.1% \downarrow (STC), 1.23% \downarrow (STG),

No change in HDL, 9.5% \downarrow (LDL)

RAW GARLIC GROUP



- Ramrati, 40 years/F
- Adult Nephrotic syndrome
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	281	300	55	60	166	3.0:1
4 week	267	262	54	52.4	160.6	3.0:1
12 week	-	-	-	-	-	-
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

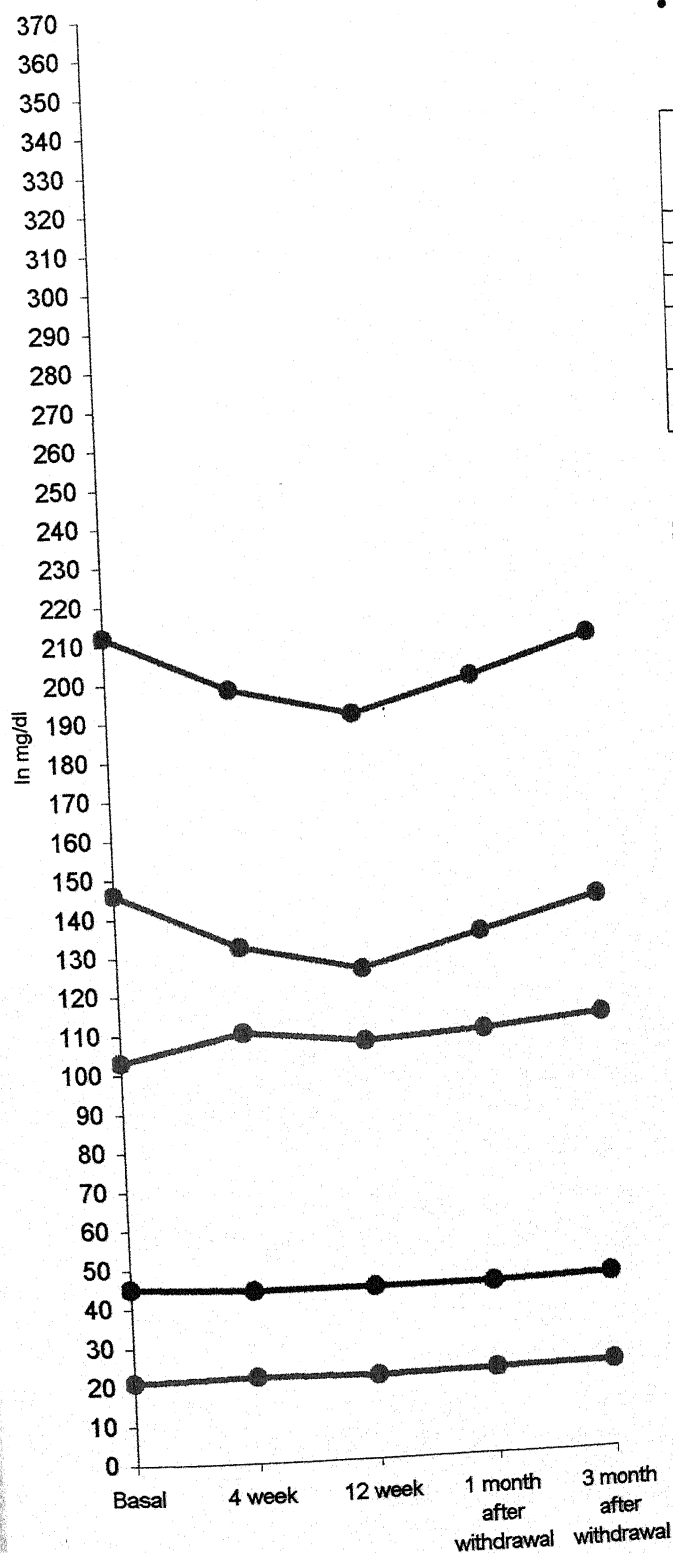
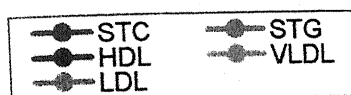
Normal HDL and High LDL

After 4 weeks of treatment –

5.0% \downarrow (STC), 12.66% \downarrow (STG),

1.81% \downarrow (HDL), 3.25% \downarrow (LDL)

RAW GARLIC GROUP



- Lila Devi, 60 years/F
- Systemic hypertension
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	212	103	45	21	146	3.2:1
4 week	198	110	44	22	132	3:1
12 week	191	107	44	21.4	125.6	2.9:1
1 month after withdrawal	200	109	44	21.8	134.2	3.0:1
3 month after withdrawal	210	112	45	22.4	142.6	3.2:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment –

6.6% \downarrow (STC), 6.8% \uparrow (STG),

2.2% \downarrow (HDL), 9.5% \downarrow (LDL)

After 12 weeks of treatment –

9.9% \downarrow (STC), 3.8% \uparrow (STG),

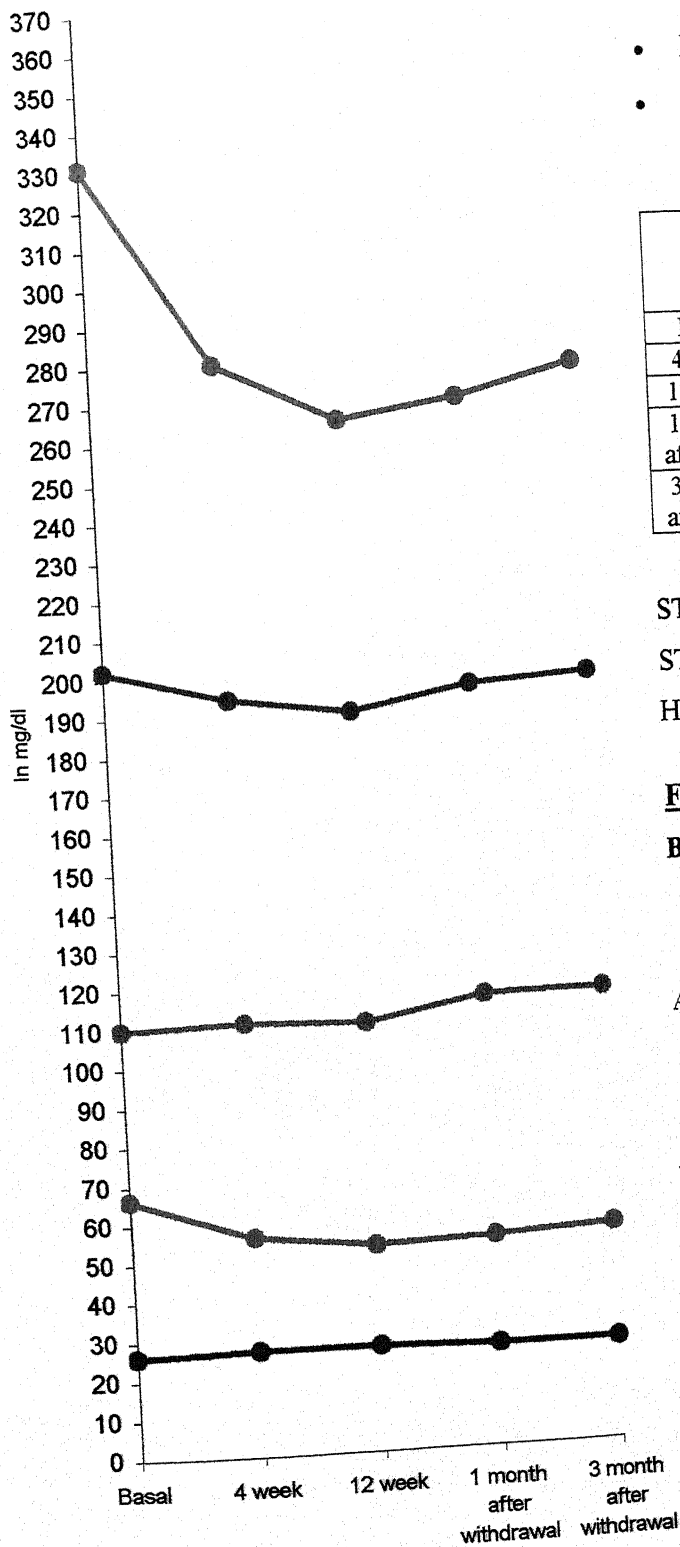
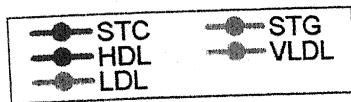
2.2% \downarrow (HDL), 13.9% \downarrow (LDL)

After 3 months of withdrawal –

0.94% \downarrow (STC), 8.7% \uparrow (STG),

No Change in HDL, 2.3% \downarrow (LDL)

RAW GARLIC GROUP



- Shanti Devi, 65 years/F
- NIDDM with diabetic nephropathy with dyslipidemia
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	202	331	26	66.2	109.8	4.2:1
4 week	194	280	27	56	111	4.1:1
12 week	190	265	27	53	110	4.1:1
1 month after with*	196	270	26	54	116	4.4:1
3 month after with*	198	278	26	55.6	116.4	4.5:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

Low HDL and High LDL

After 4 weeks of treatment –

3.96% \downarrow (STC), 15.4% \downarrow (STG),

3.8% \uparrow (HDL), 1.09% \uparrow (LDL)

After 12 weeks of treatment –

5.9% \downarrow (STC), 19.9% \downarrow (STG),

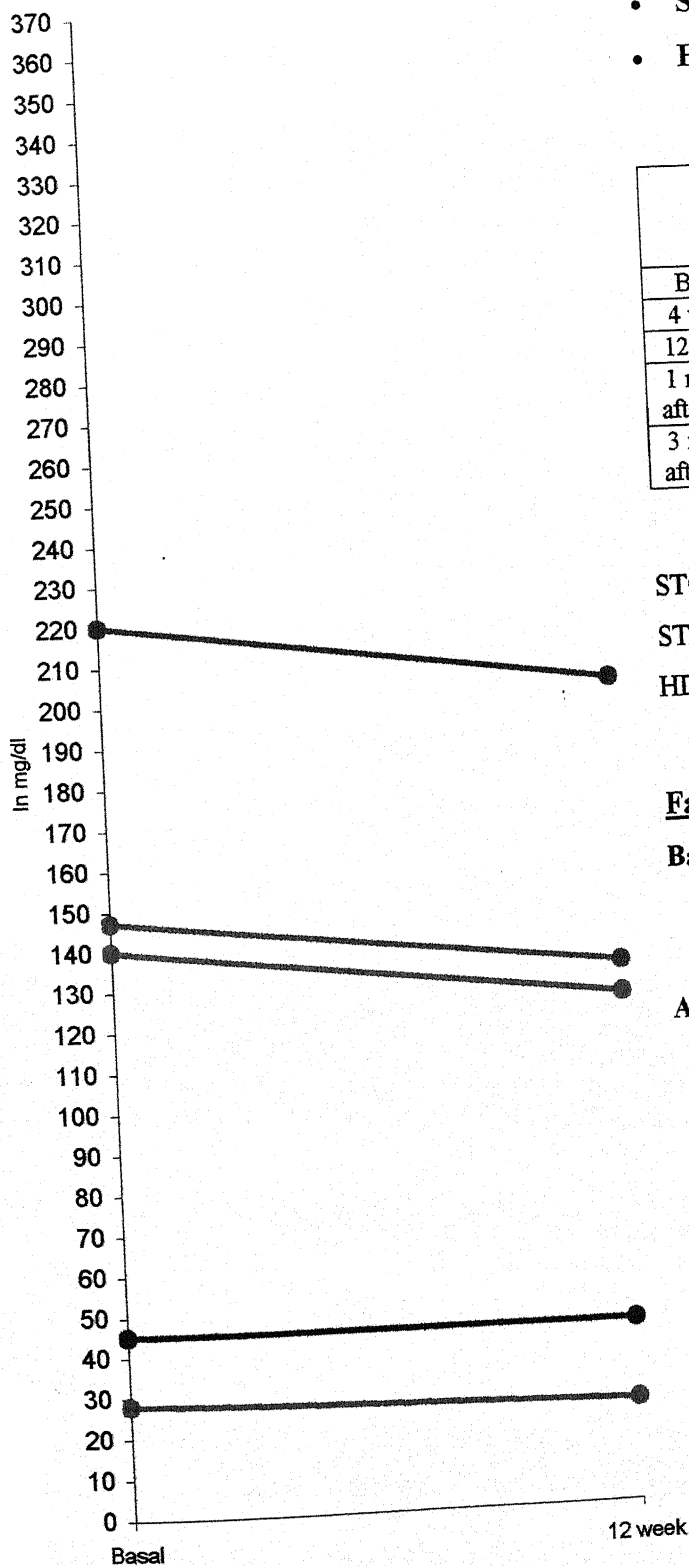
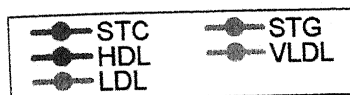
3.8% \uparrow (HDL), 0.19% \uparrow (LDL)

After 3 months of withdrawal –

1.9% \downarrow (STC), 16.0% \downarrow (STG),

No change in HDL, 6.0% \uparrow (LDL)

RAW GARLIC GROUP



- Dinesh Kumar Gupta,
43 years/M
- Systemic hypertension
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	220	140	45	28	147	3.3:1
4 week	-	-	-	-	-	-
12 week	204	126	45	25.2	133.8	3.0:1
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

$$\text{STC } 1 \text{ mmol/L} = 38.76 \text{ mg/dl}$$

$$\text{STG mmol/L} = \text{mg/dl} \times 0.0114$$

$$\text{HDL mmol/L} = \text{mg/dl} / 38.76$$

Fasting values :

Basal –

High STC, Normal STG,

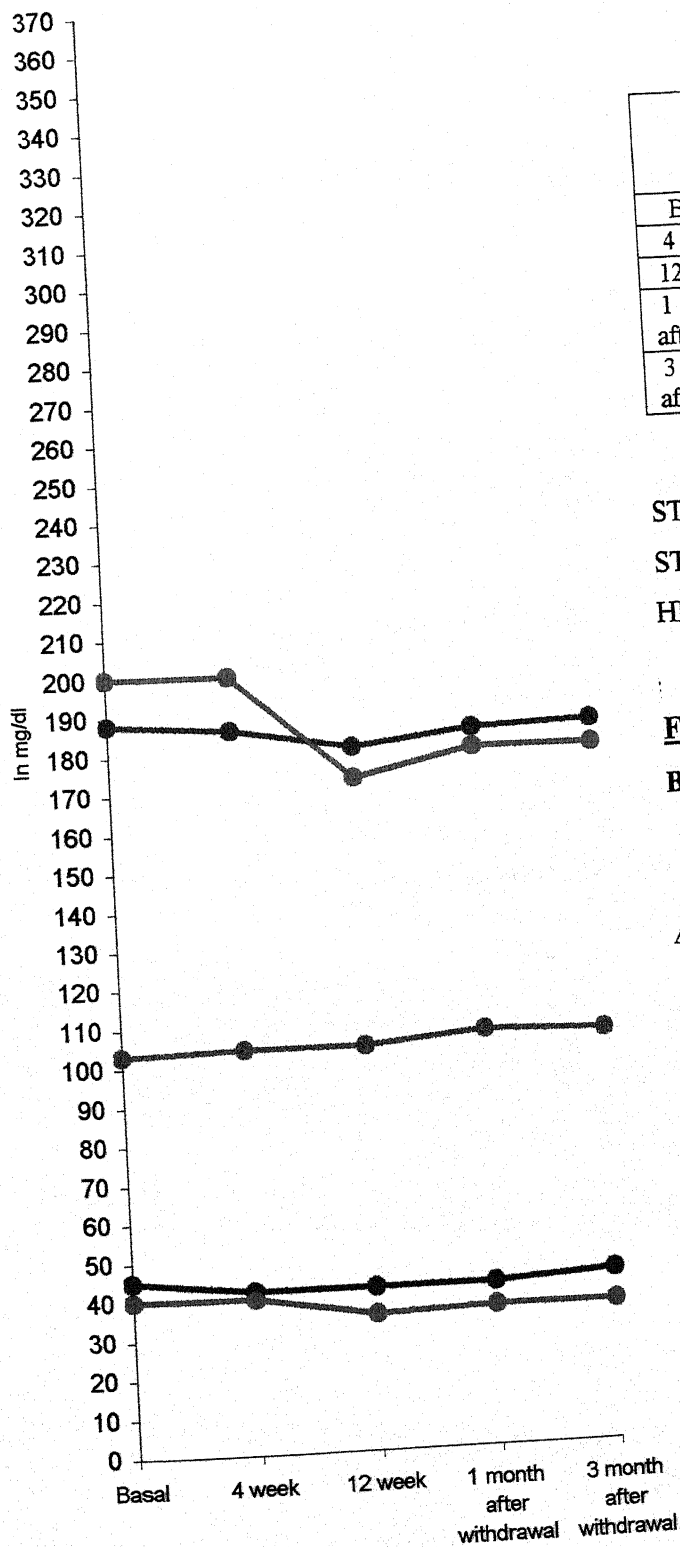
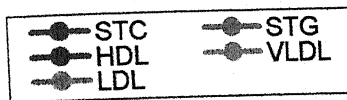
Normal HDL and High LDL

After 12 weeks of treatment –

7.2% ↓ (STC), 10% ↓ (STG),

No change in HDL, 8.9% ↓ (LDL)

GARLIC PEARLS GROUP



- S.A. Kadri, 42 years/M
- Lateral wall ischemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	188	200	45	40	103	2.2:1
4 week	186	200	42	40	104	2.4:1
12 week	181	173	42	35	104	2.4:1
1 month after with	185	180	42	36	107	2.5:1
3 month after with	186	180	44	36	106	2.4:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

Normal STC, High STG,

Normal HDL and High LDL

After 4 weeks of treatment –

1.07% \downarrow (STC), No change in STG,

6.6% \downarrow (HDL), 0.97% \uparrow (LDL)

After 12 weeks of treatment –

3.72% \downarrow (STC), 13.5% \downarrow (STG),

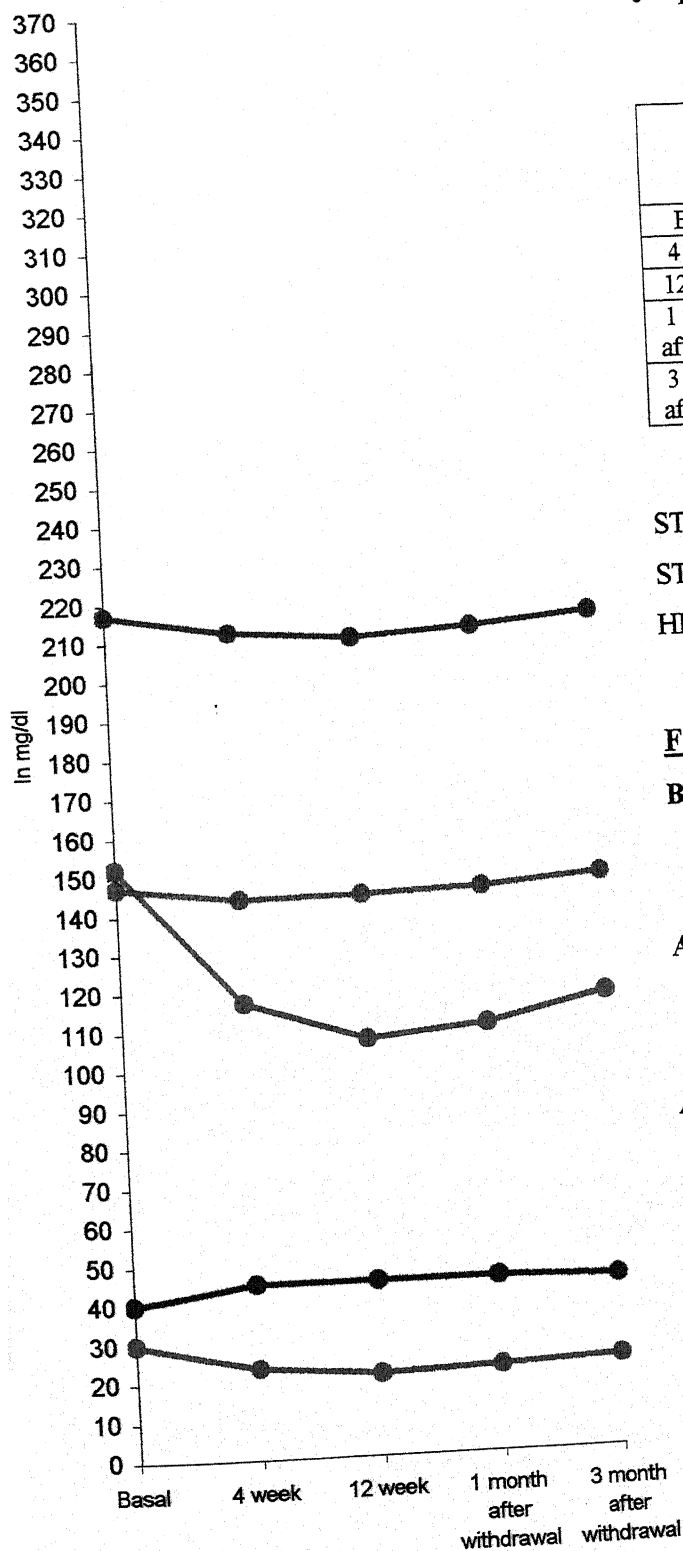
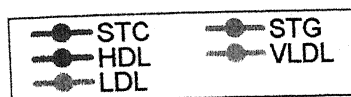
6.6% \downarrow (HDL), 0.97% \uparrow (LDL)

After 3 months of withdrawal –

1.06% \downarrow (STC), 10% \downarrow (STG),

2.2% \downarrow (HDL), 2.91% \uparrow (LDL)

GARLIC PEARLS GROUP



- M. Barua, 45 years/F
- Systemic hypertension
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	217	152	40	30	147	3.6:1
4 week	212	117	45	23.4	143.6	3.1:1
12 week	210	107	45	21	144	3.1:1
1 month after with	212	110	45	22	145	3.2:1
3 month after with	215	117	44	23.4	147.6	3.3:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment -

2.3% \downarrow (STC), 23% \downarrow (STG),

12.5% \uparrow (HDL), 2.3% \downarrow (LDL)

After 12 weeks of treatment -

3.2% \downarrow (STC), 29.6% \downarrow (STG),

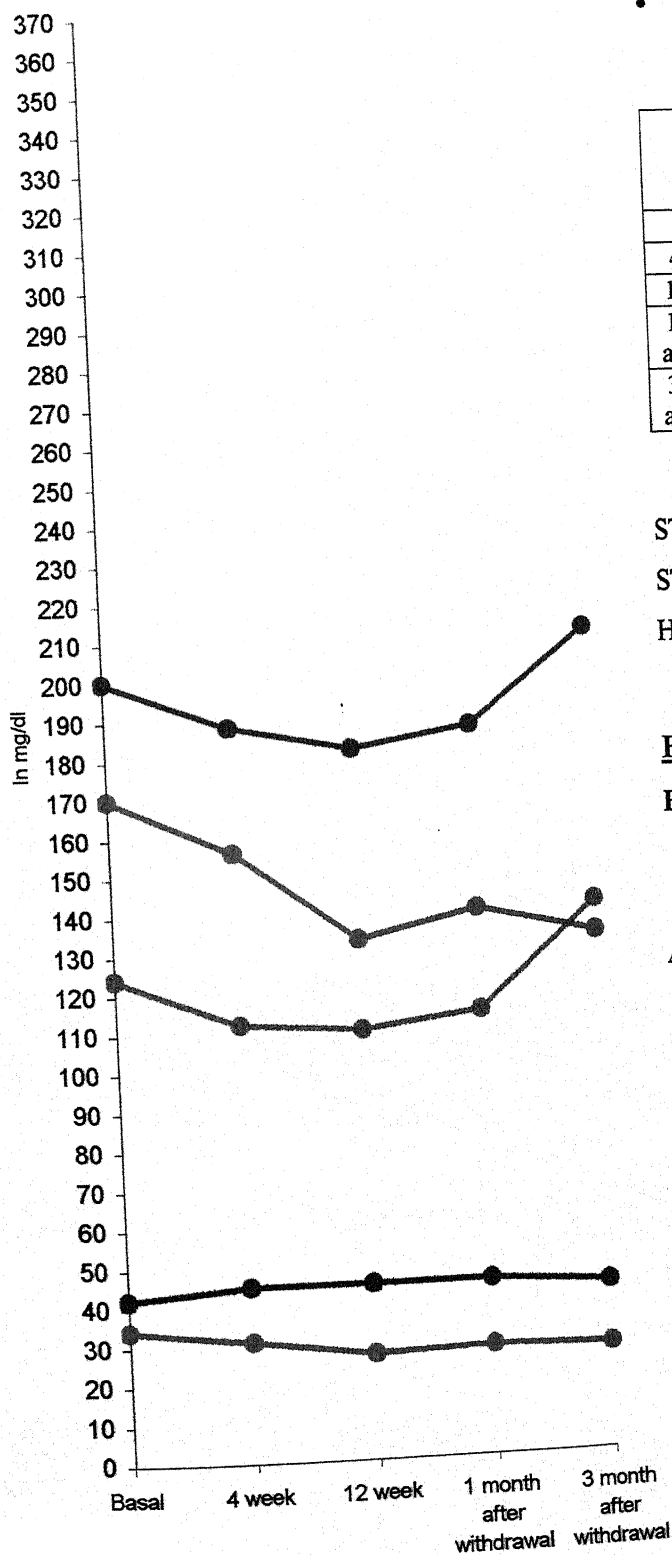
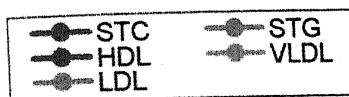
12.5% \uparrow (HDL), 2.0% \uparrow (LDL)

After 3 months of withdrawal -

0.92% \downarrow (STC), 23% \downarrow (STG),

10% \uparrow (HDL), 0.4% \uparrow (LDL)

GARLIC PEARLS GROUP



- Sunil Kumar, 35 years/M
- Systemic hypertension
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	200	170	42	34	124	2.9:1
4 week	188	156	45	31	112	2.5:1
12 week	182	133	45	27	110	2.4:1
1 month after with	187	140	45	28	114	2.5:1
3 month after with	211	133	43	27	141	3.2:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment –

6% \downarrow (STC), 8.2% \downarrow (STG),

7.1% \uparrow (HDL), 9.6% \downarrow (LDL)

After 12 weeks of treatment –

9% \downarrow (STC), 21.7% \downarrow (STG),

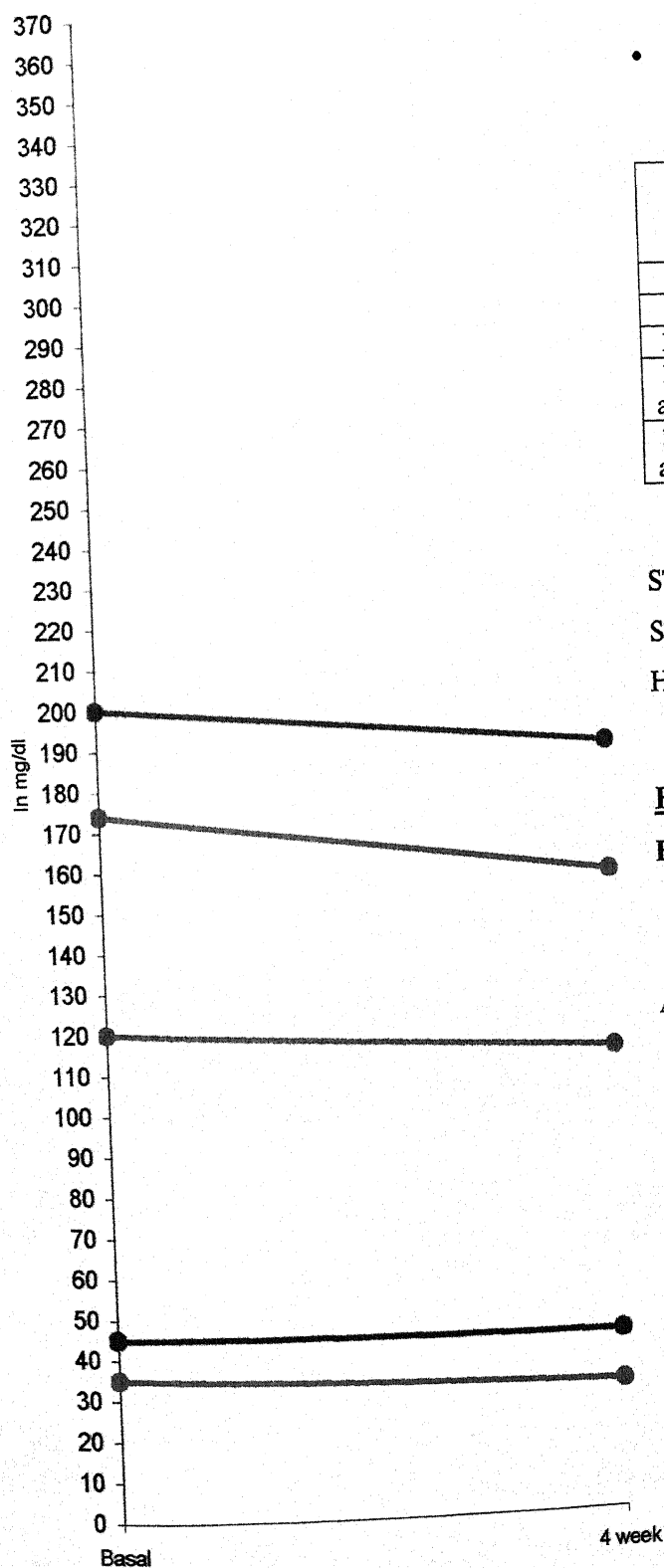
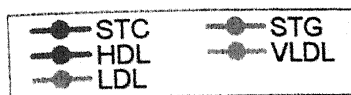
7.1% \uparrow (HDL), 11.2% \downarrow (LDL)

After 3 months of withdrawal –

5.5% \uparrow (STC), 21.7% \downarrow (STG),

2.3% \uparrow (HDL), 13.7% \uparrow (LDL)

GARLIC PEARLS GROUP



- Hanuman Prasad, 66 years/M
- Cellulitis with post infectious glomerulonephritis
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	200	174	45	35	120	2.7:1
4 week	190	158	44	31.6	114.4	2.6:1
12 week	-	-	-	-	-	-
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

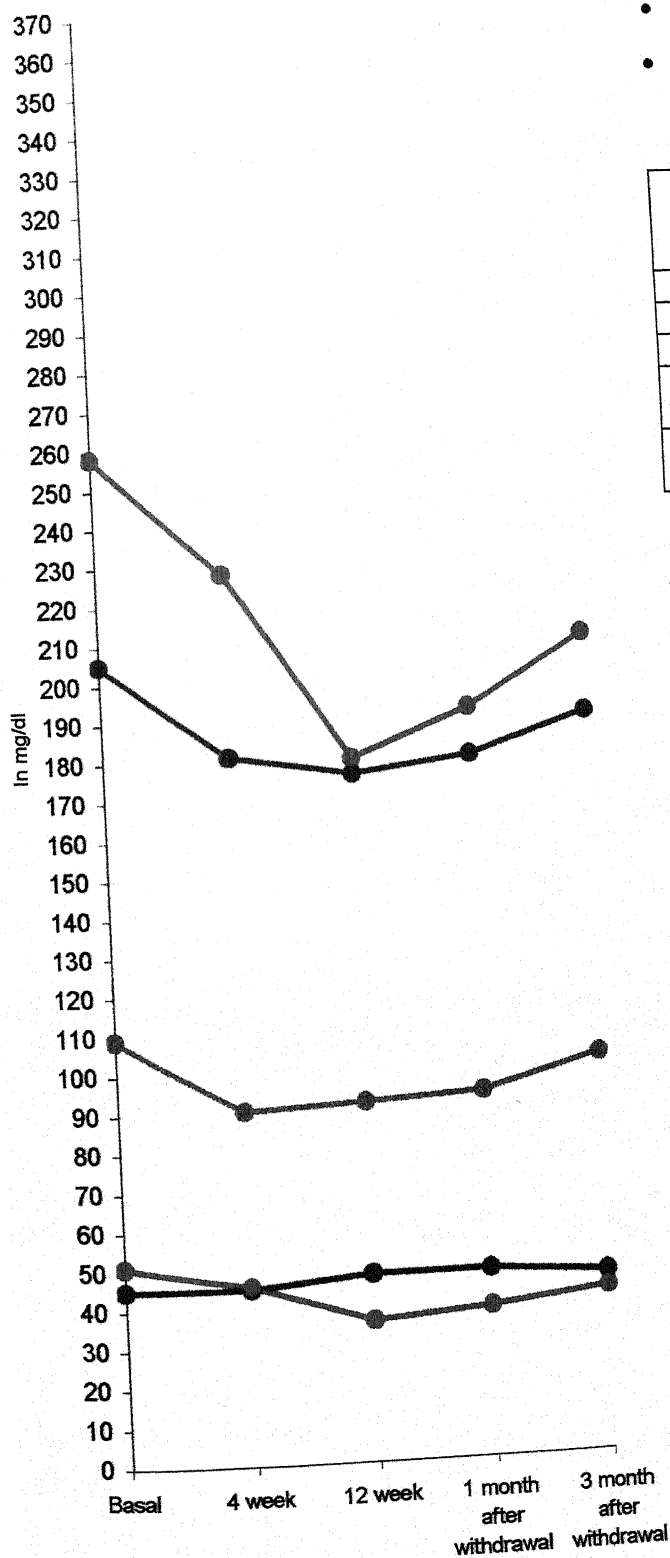
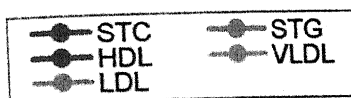
Normal HDL and High LDL

After 4 weeks of treatment –

5% \downarrow (STC), 9.19% \downarrow (STG),

2.2% \downarrow (HDL), 4.6% \downarrow (LDL)

GARLIC PEARLS GROUP



- Ashok Srivastava, 39 years/M
- Systemic hypertension
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	205	258	45	51.0	109	2.5:1
4 week	181	228	45	45.6	90.4	2:1
12 week	176	180	48	36.0	92.0	1.9:1
1 month after with*	180	192	48	38.4	93.6	1.9:1
3 month after with*	190	210	46	42.0	102	2.2:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

Normal HDL and High LDL

After 4 weeks of treatment –

11.7% \downarrow (STC), 11.6% \downarrow (STG),

No change in HDL, 17.06% \downarrow (LDL)

After 12 weeks of treatment –

14.1% \downarrow (STC), 30% \downarrow (STG),

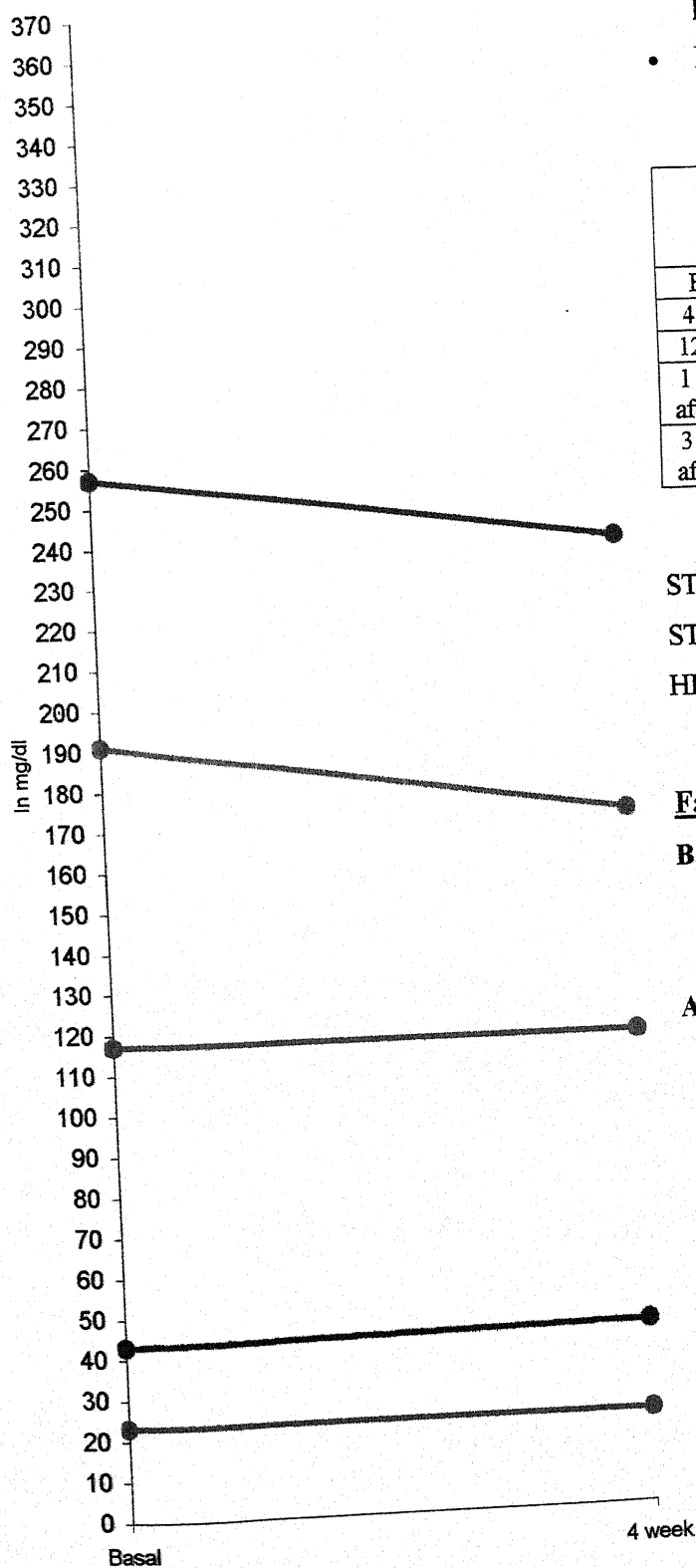
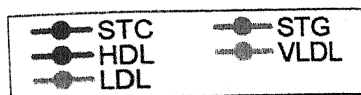
6.6% \uparrow (HDL), 15.5% \downarrow (LDL)

After 3 months of withdrawal –

7.3% \downarrow (STC), 18.6% \downarrow (STG),

2.1% \uparrow (HDL), 6.4% \downarrow (LDL)

GARLIC PEARLS GROUP



- Kamta Prasad, 50 years/M
- Adult nephrotic syndrome with pulmonary TB
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	257	117	43	23	191	4.4:1
4 week	240	117	45	23	172	3.8:1
12 week	-	-	-	-	-	-
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, Normal STG,

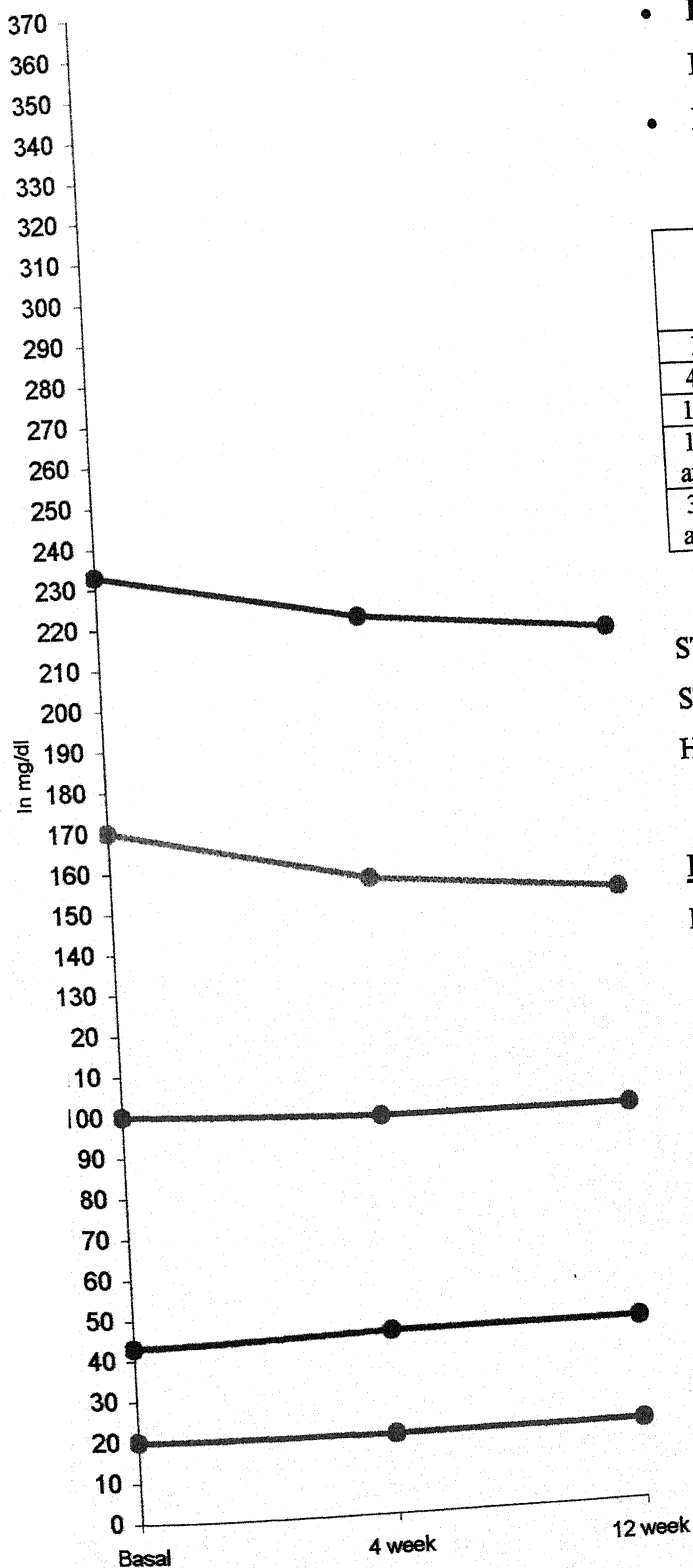
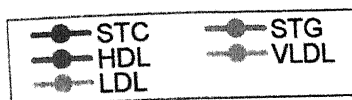
Normal HDL and High LDL

After 4 weeks of treatment -

6.6% \downarrow (STC), No change in STG,

4.6% \uparrow (HDL), 9.9% \downarrow (LDL)

GARLIC PEARLS GROUP



- Chandrashekar Diwedi,
52 years/M
- Extensive anterior wall MI with
R.B.B.B.
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	233	100	43	20	170	3.9:1
4 week	221	98	45	19.6	156.4	3.5:1
12 week	216	98	45	19.6	151.4	3.4:1
1 month after with*	-	-	-	-	-	-
3 month after with*	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment -

5.2% \downarrow (STC), 2% \downarrow (STG),

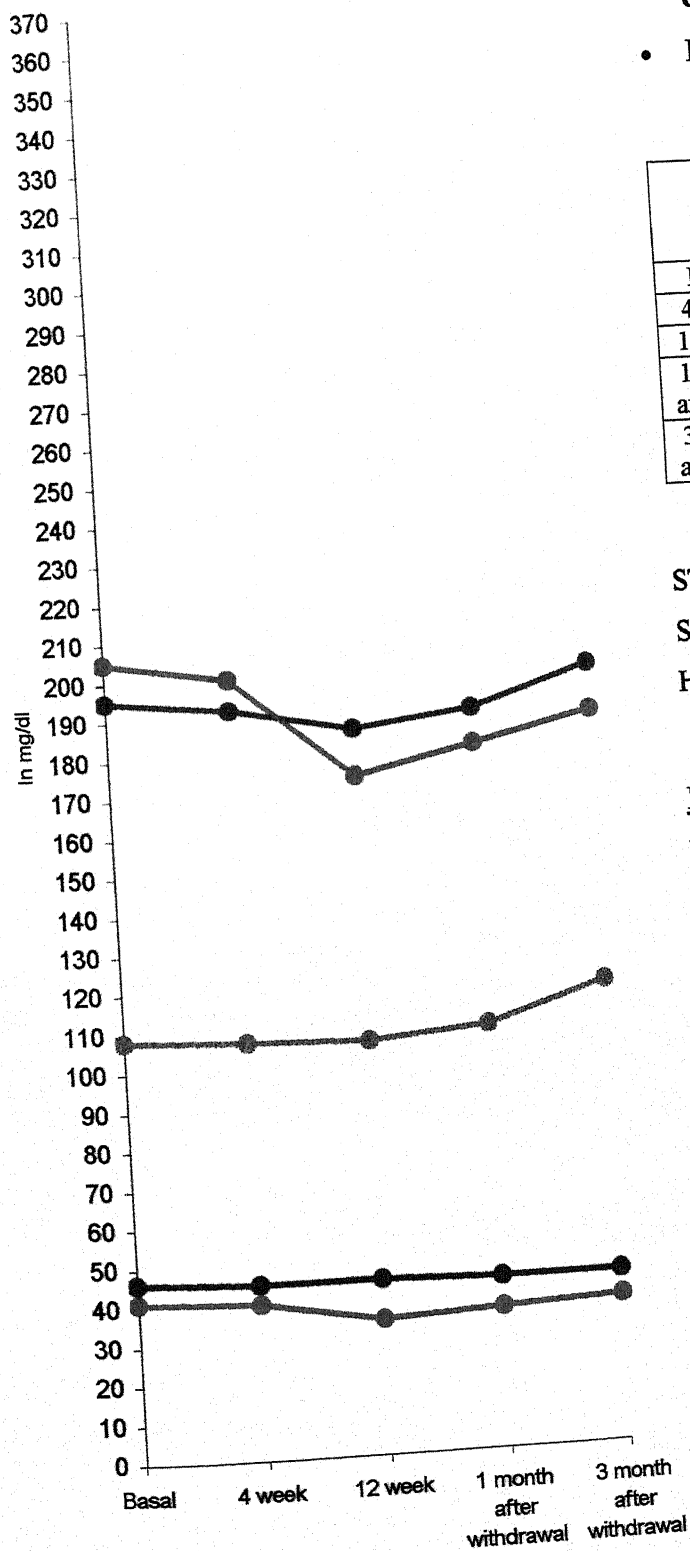
4.7% \uparrow (HDL), 8% \downarrow (LDL)

After 12 weeks of treatment -

7.3% \downarrow (STC), 2% \downarrow (STG),

4.7% \uparrow (HDL), 10.9% \downarrow (LDL)

GARLIC PEARLS GROUP



- Ramgopal K., 50 years/M
- Systemic hypertension with acute coronary syndrome
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	195	205	46	41	108	2.3:1
4 week	192	200	45	40	107	2.4:1
12 week	186	174	45	34.8	106.2	2.3:1
1 month after with*	190	181	44	36.2	108.8	2.5:1
3 month after with*	200	188	44	37.6	118.4	2.7:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

Normal STC, high STG,

Normal HDL and High LDL

After 4 weeks of treatment -

1.5% \downarrow (STC), 2.4% \downarrow (STG),

2.1% \uparrow (HDL), 0.92% \downarrow (LDL)

After 12 weeks of treatment -

4.6% \downarrow (STC), 15.1% \downarrow (STG),

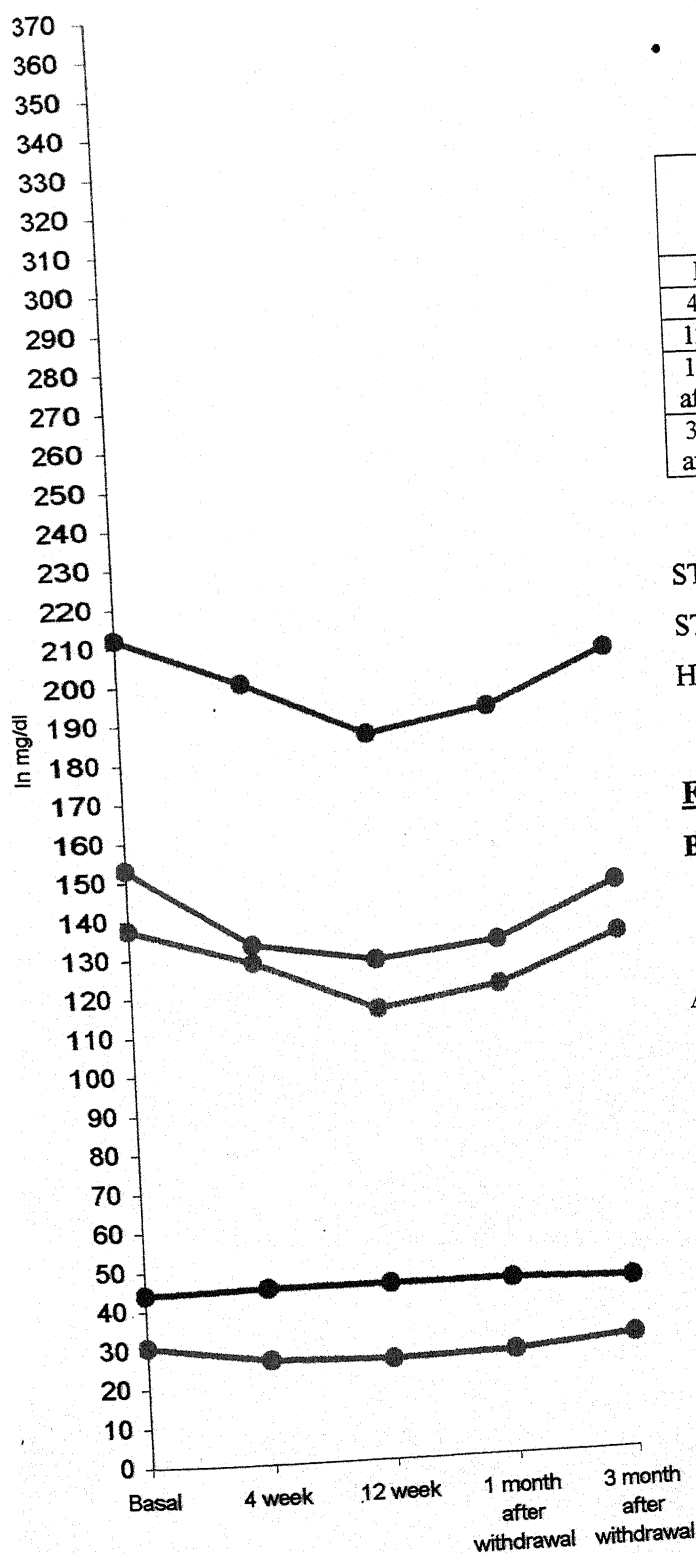
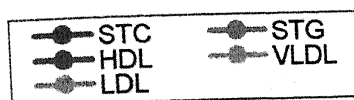
2.1% \downarrow (HDL), 1.7% \downarrow (LDL)

After 3 months of withdrawal -

2.5% \uparrow (STC), 8.2% \downarrow (STG),

4.2% \downarrow (HDL), 9.6% \uparrow (LDL)

GARLIC PEARLS GROUP



- Omar Mohammad, 60 years/M
- Acute inferior wall MI with antero-lateral ischemia
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	212	153	44	30.6	137.4	3.1:1
4 week	200	133	45	26.6	128.4	2.8:1
12 week	186	128	45	25.6	115.4	2.6:1
1 month after with*	192	132	45	26.4	120.6	2.7:1
3 month after with*	206	146	44	29.2	132.8	3.0:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment –

5.6% \downarrow (STC), 13% \downarrow (STG),

2.2% \uparrow (HDL), 6.5% \downarrow (LDL)

After 12 weeks of treatment –

12.26% \downarrow (STC), 16.3% \downarrow (STG),

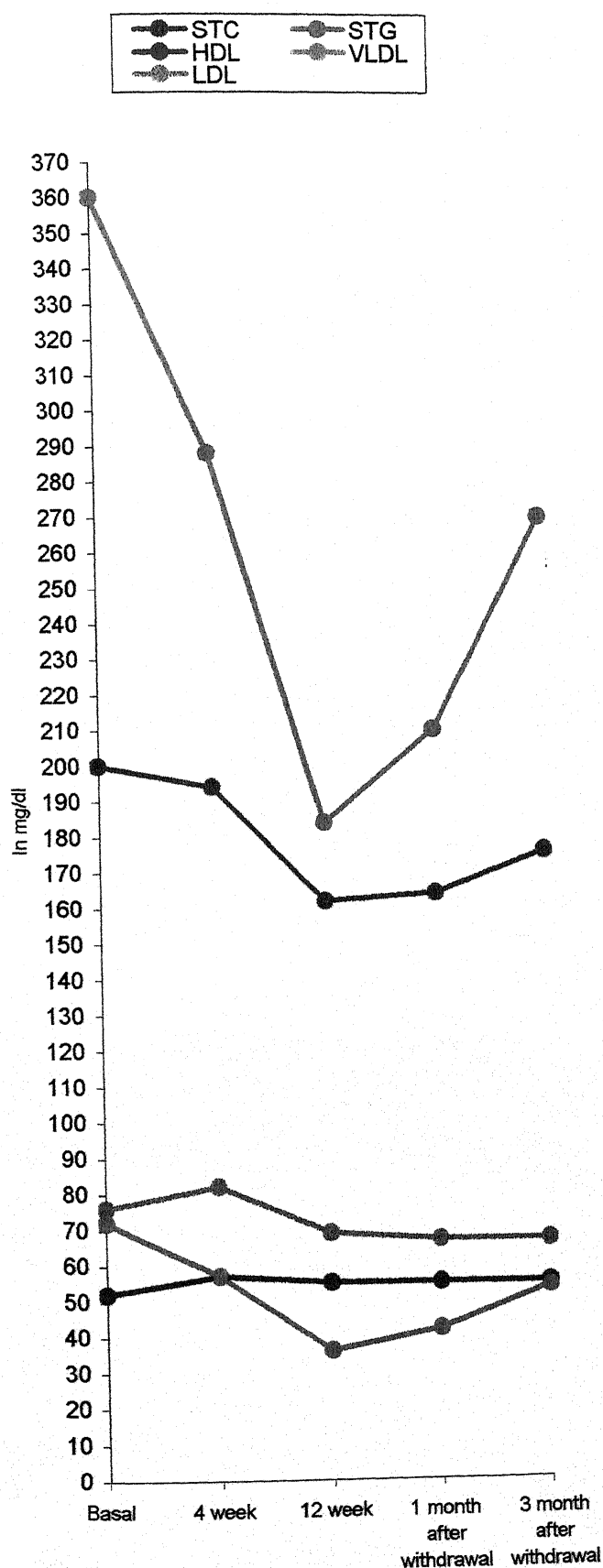
2.2% \uparrow (HDL), 16% \downarrow (LDL)

After 3 months of withdrawal –

2.8% \downarrow (STC), 4.5% \downarrow (STG),

No change in HDL, 3.3% \downarrow (LDL)

SIMVASTATIN GROUP



- Sunil Khattar, 53 years/M
- Diabetes Mellitus
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	200	360	52	72	76	1.4:1
4 week	194	288	55	57	82	1.4:1
12 week	162	184	57	36	69	1.2:1
1 month after with*	164	210	55	42	67	1.2:1
3 month after with*	176	270	55	54	67	1.2:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

Normal HDL and Normal LDL

After 4 weeks of treatment –

3% ↓(STC), 20% ↓(STG),

5.8% ↑(HDL), 7.8% ↑(LDL)

After 12 weeks of treatment –

19% ↓ (STC), 48% ↓(STG),

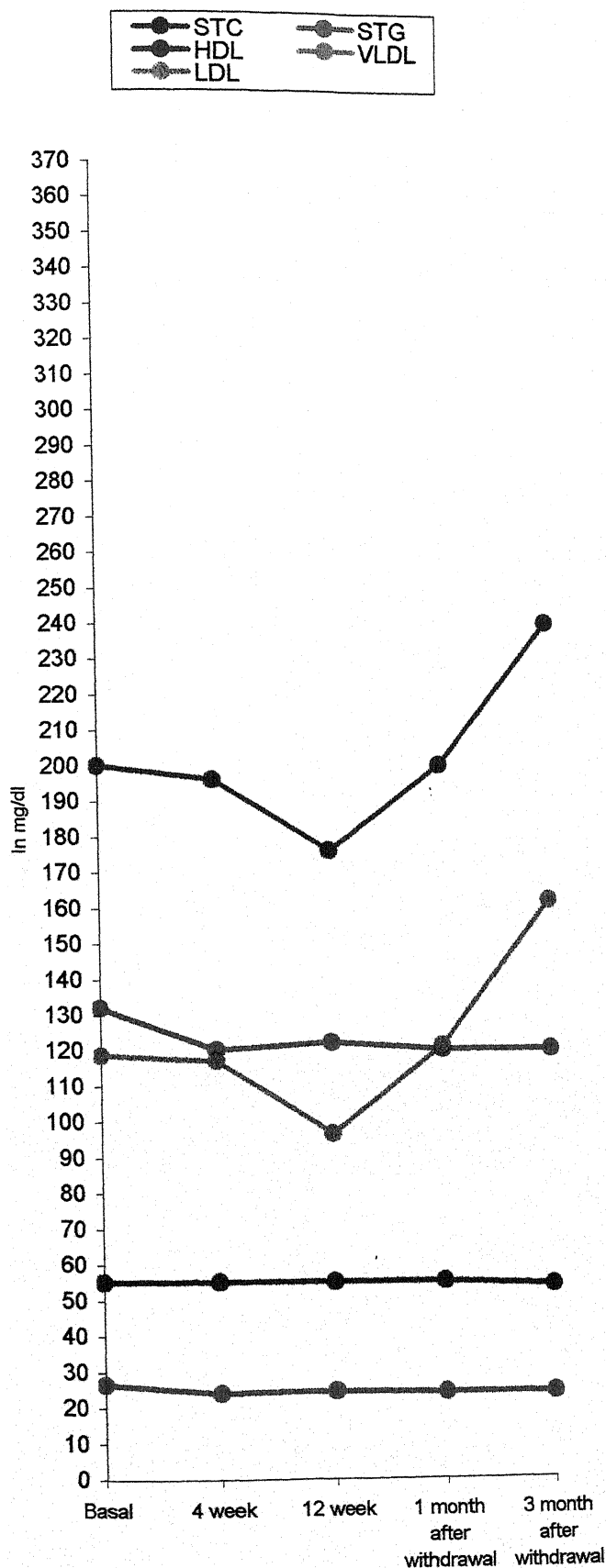
9.6% ↑ (HDL), 9.2% ↓ (LDL)

After 3 months of withdrawal –

12% ↓ (STC), 30% ↓(STG),

5.8% ↑ (HDL), 13.4% ↓ (LDL)

SIMVASTATIN GROUP



- Laxmi Bai, 60 years/F
- Diabetes mellitus with old anterior wall MI with diabetic nephropathy
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	200	132	55	26.4	118.6	2.2:1
4 week	196	120	55	24.0	117	2.2:1
12 week	176	122	55	24.4	96.6	1.8:1
1 month after with	200	120	55	24.0	121	2.2:1
3 month after with	240	120	54	24.0	162	3:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment –

2% \downarrow (STC), 9.0% \downarrow (STG),

No change in HDL, 1.3% \downarrow (LDL)

After 12 weeks of treatment –

12% \downarrow (STC), 7.5% \downarrow (STG),

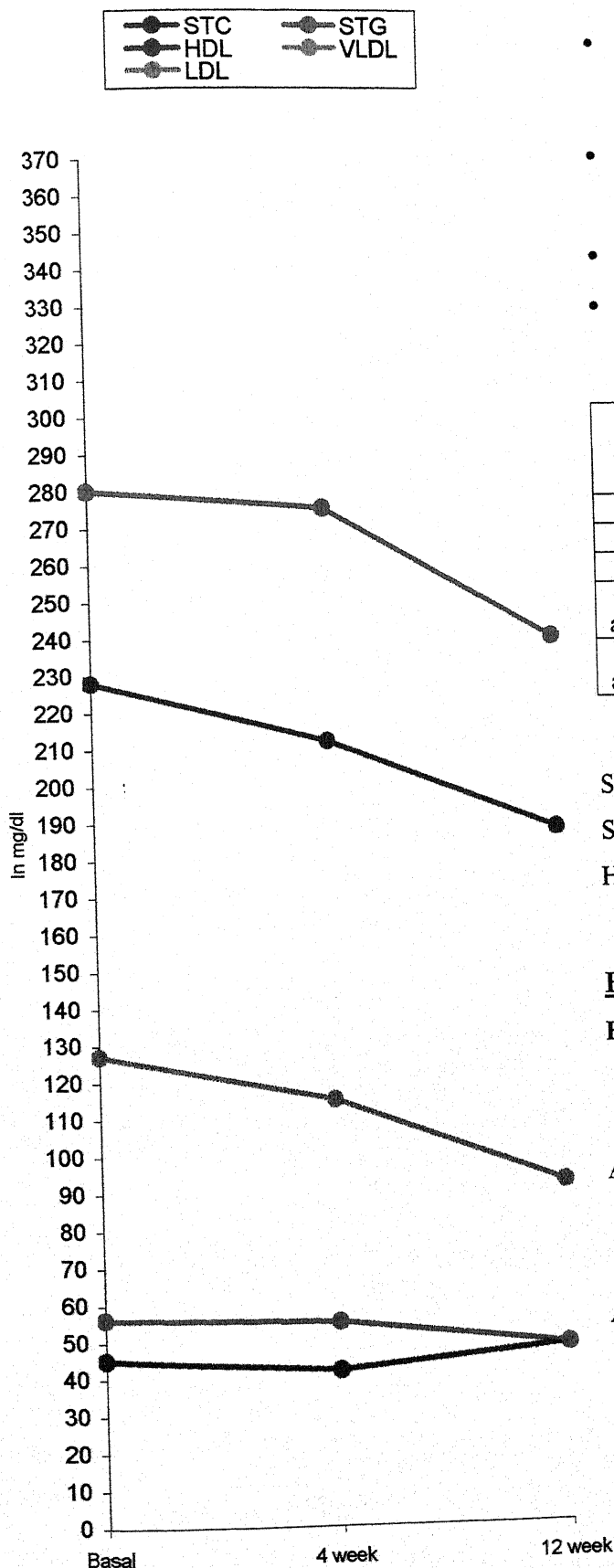
No change in HDL, 18.5% \downarrow (LDL)

After 3 months of withdrawal –

20% \uparrow (STC), 9.0% \downarrow (STG),

1.8% \downarrow (HDL), 36.5% \uparrow (LDL)

SIMVASTATIN GROUP



- Prabhudayal Yadav,
40 years/M
- CAD, unstable angina, old inferior wall MI
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	228	280	45	56	127	2.8:1
4 week	212	275	42	55	115	2.7:1
12 week	188	240	48	48	92	1.9:1
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

Normal HDL and High LDL

After 4 weeks of treatment –

7.0% \downarrow (STC), 1.7% \downarrow (STG),

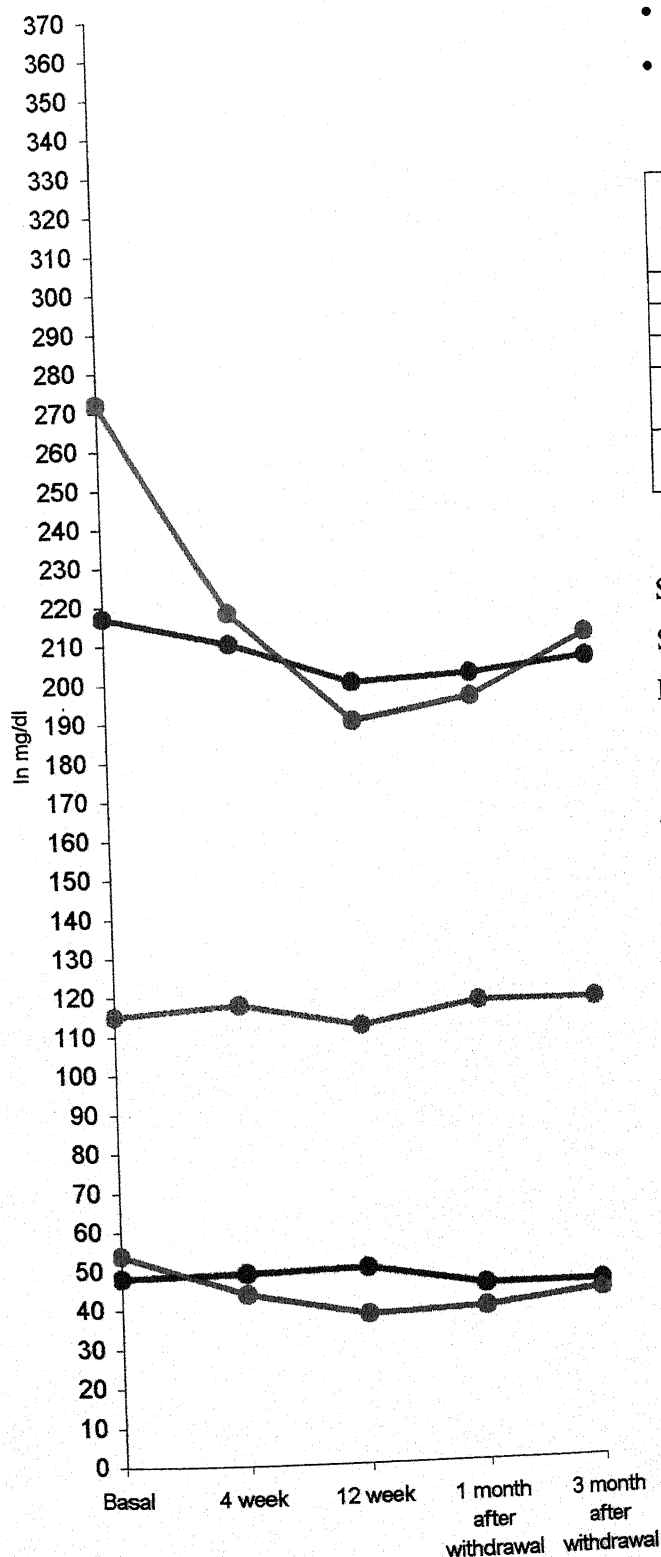
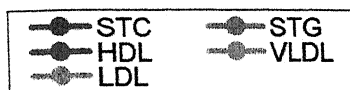
6.6% \downarrow (HDL), 9.4% \downarrow (LDL)

After 12 weeks of treatment –

17.5% \downarrow (STC), 14.2% \downarrow (STG),

6.6% \uparrow (HDL), 27.5% \downarrow (LDL)

SIMVASTATIN GROUP



- Santosh Jain, 42 years/M
- Unstable angina
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	217	272	48	54.0	115.0	2.4:1
4 week	210	218	49	43.6	117.4	2.4:1
12 week	200	190	50	38.0	112.0	2.2:1
1 month after with*	202	196	45	39.2	117.8	2.6:1
3 month after with*	206	212	45	43.0	118.0	2.6:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, High STG,

Normal HDL and High LDL

After 4 weeks of treatment -

3.2% \downarrow (STC), 19.8% \downarrow (STG),

2.0% \uparrow (HDL), 2.0% \uparrow (LDL)

After 12 weeks of treatment -

8.5% \downarrow (STC), 30% \downarrow (STG),

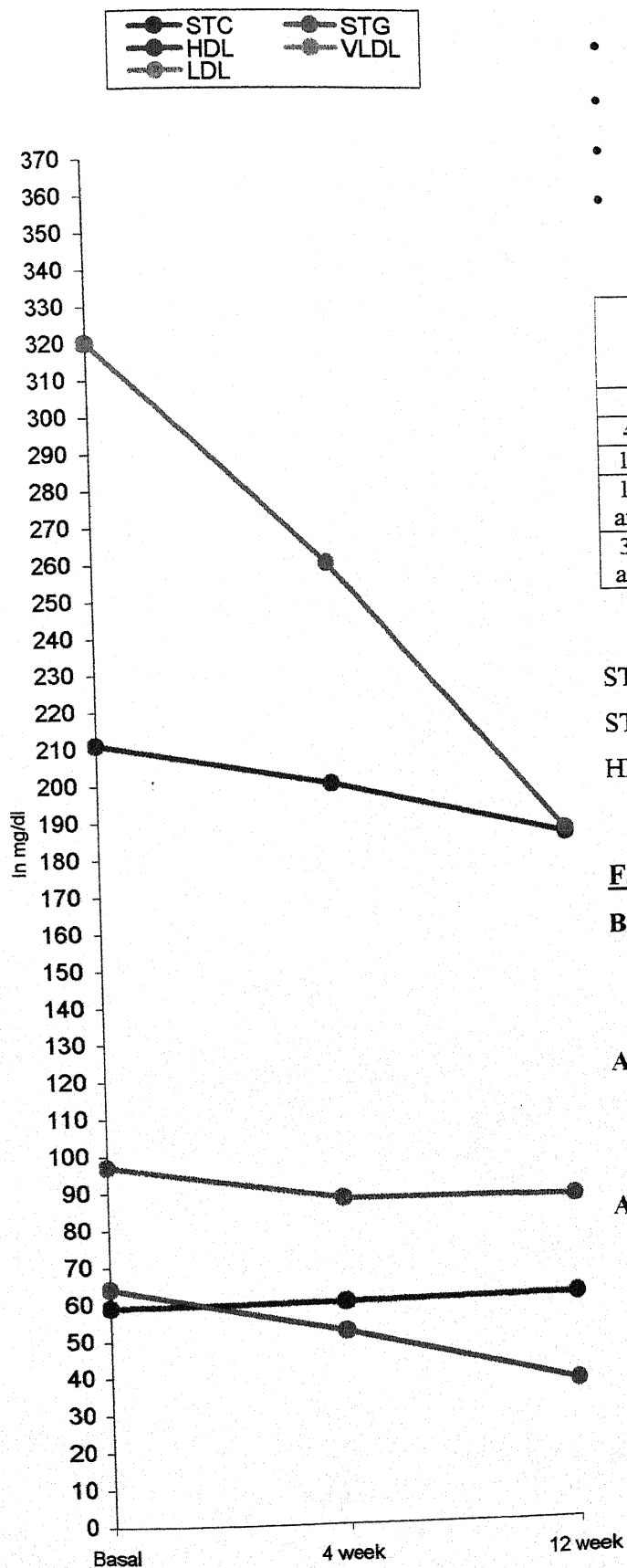
4.1% \uparrow (HDL), 2.6% \downarrow (LDL)

After 3 months of withdrawal -

5.0% \downarrow (STC), 22% \downarrow (STG),

6.25% \downarrow (HDL), 2.6% \uparrow (LDL)

SIMVASTATIN GROUP



- Meera Bai, 36 years/F
- Stable angina
- Hypercholesterolemia
- Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	211	320	59	64	97	1.9:1
4 week	200	260	60	52	88	1.4:1
12 week	186	187	61	37.4	87.6	1.4:1
1 month after with	-	-	-	-	-	-
3 month after with	-	-	-	-	-	-

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

Normal HDL and Normal LDL

After 4 weeks of treatment –

5.2% \downarrow (STC), 18.8% \downarrow (STG),

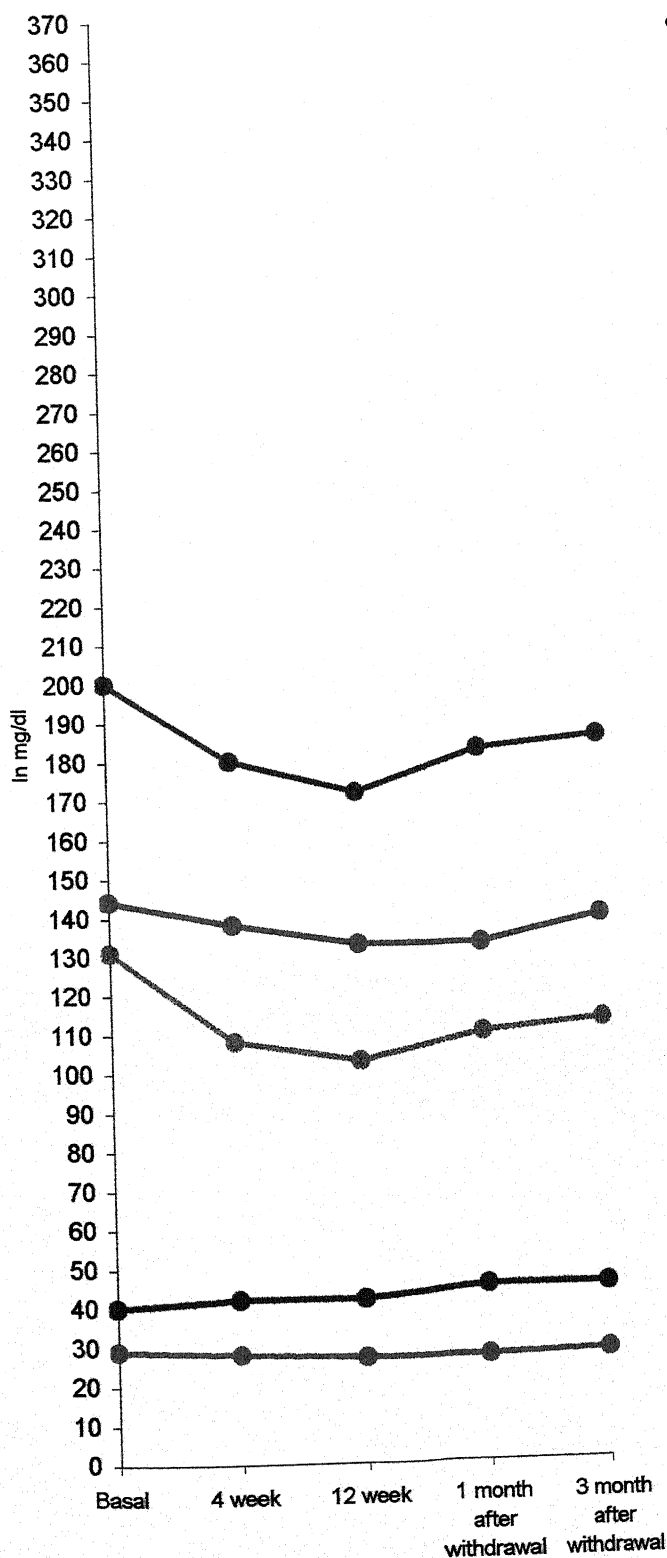
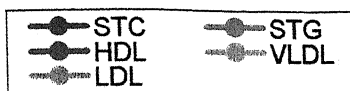
1.6% \uparrow (HDL), 9.27% \downarrow (LDL)

After 12 weeks of treatment –

11.8% \downarrow (STC), 41.5% \downarrow (STG),

3.3% \uparrow (HDL), 9.6% \downarrow (LDL)

SIMVASTATIN GROUP



- Harnarayan, 50 years/M
- Anterior wall MI
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	200	144	40	29	131	3.2:1
4 week	180	138	42	28	108	2.6:1
12 week	172	133	42	27	103	2.5:1
1 month after with*	183	133	45	27	110	2.4:1
3 month after with*	186	140	45	28	113	2.5:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Low STG,

Normal HDL and High LDL

After 4 weeks of treatment –

10% \downarrow (STC), 4.1% \downarrow (STG),

5% \uparrow (HDL), 17.5% \downarrow (LDL)

After 12 weeks of treatment –

14% \downarrow (STC), 7.6% \downarrow (STG),

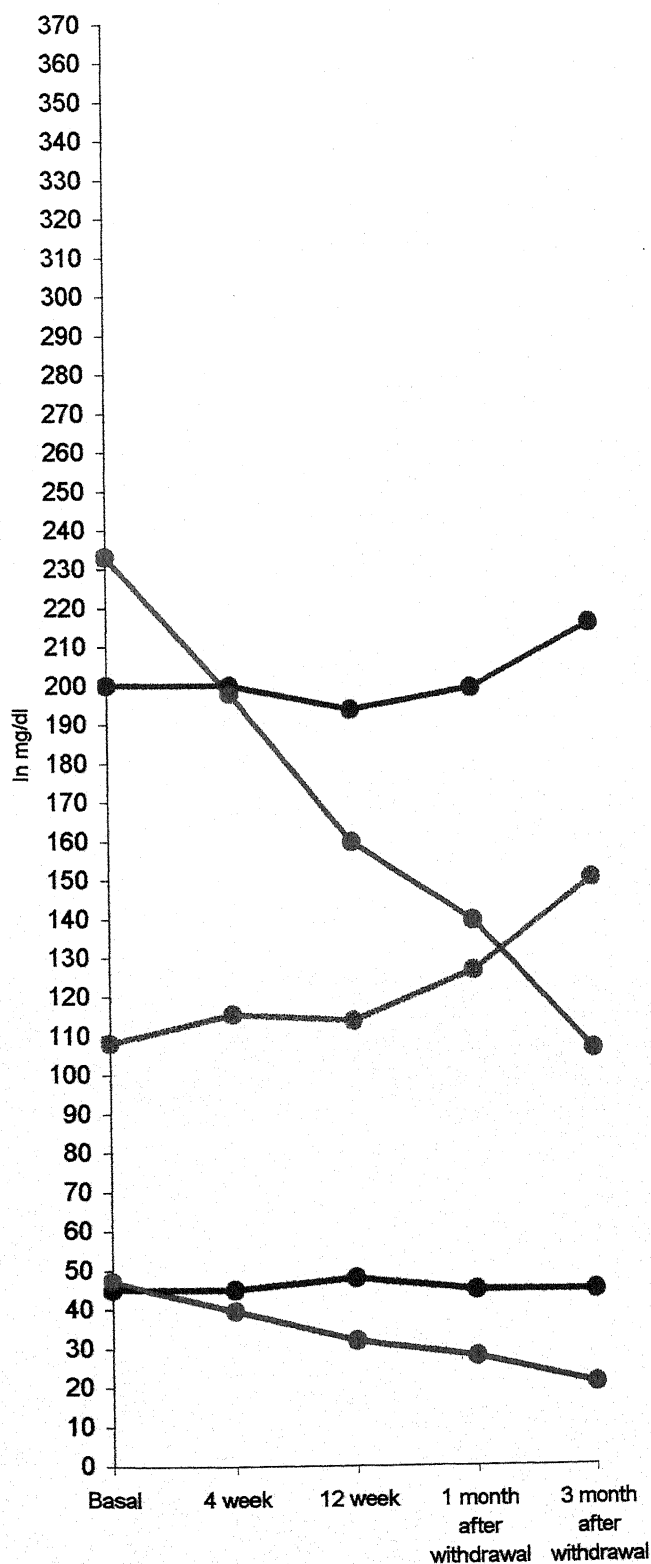
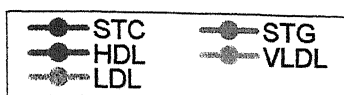
5% \uparrow (HDL), 21.3% \downarrow (LDL)

After 3 months of withdrawal –

7% \downarrow (STC), 2.8% \downarrow (STG),

12.5% \uparrow (HDL), 13.7% \downarrow (LDL)

SIMVASTATIN GROUP



• D.C. Puneet, 68 years/M

• Systemic hypertension

• Hypercholesterolemia

• Hypertriglyceridemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	200	233	45	47.0	108.0	2.4:1
4 week	200	198	45	39.6	115.4	2.6:1
12 week	194	160	48	32.0	114.0	2.3:1
1 month after with*	200	140	45	28.0	127.0	2.8:1
3 month after with*	217	107	45	21.0	151.0	3.3:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, High STG,

Normal HDL and High LDL

After 4 weeks of treatment –

No change in STC, 15% \downarrow (STG),

No change in HDL, 6.8% \uparrow (LDL)

After 12 weeks of treatment –

3% \downarrow (STC), 31.3% \downarrow (STG),

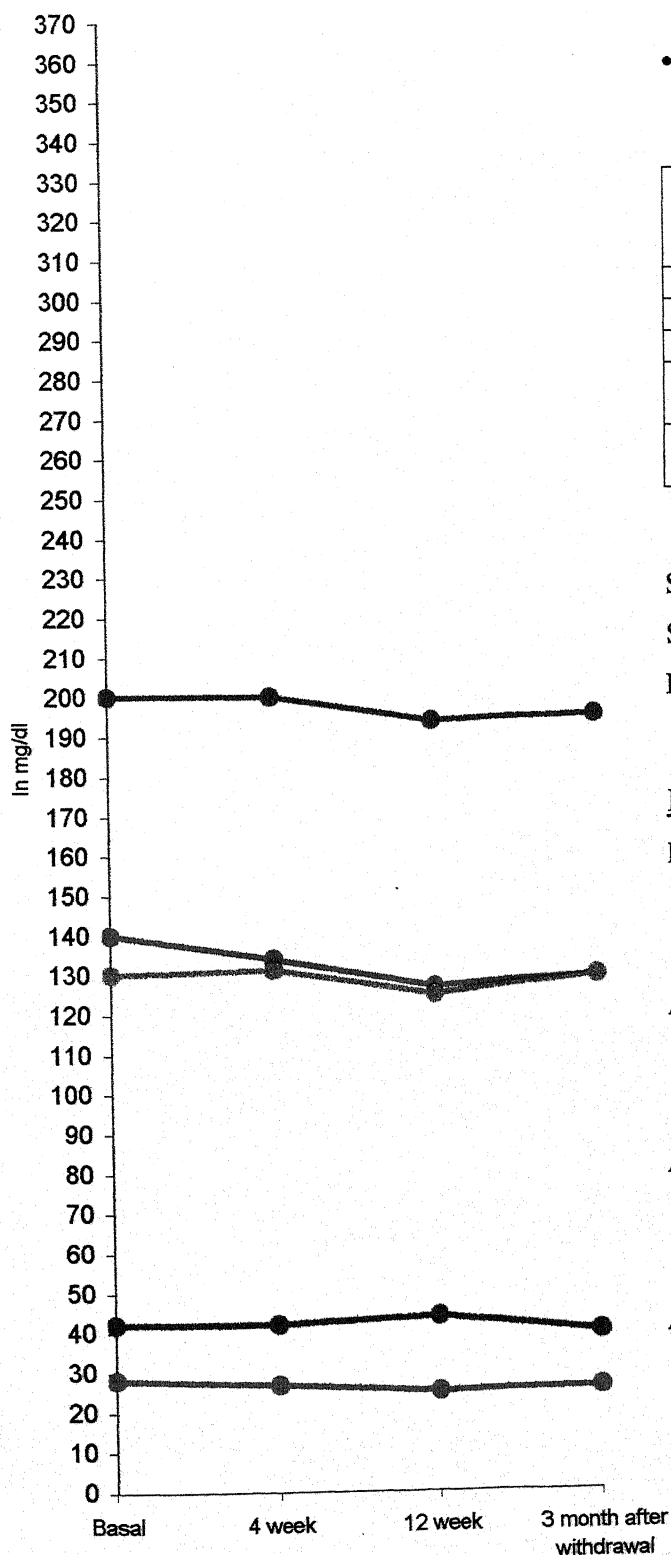
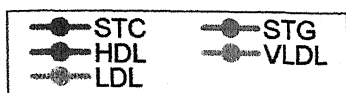
6.6% \uparrow (HDL), 5.5% \uparrow (LDL)

After 3 months of withdrawal –

8.5% \uparrow (STC), 54% \downarrow (STG),

No change in HDL, 39.8% \uparrow (LDL)

SIMVASTATIN GROUP



- K.V. Nayak, 43 years/M
- Acute inferior wall MI with systemic hypertension
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/ HDL
Basal	200	140	42	28.0	130.0	3:1
4 week	200	134	42	26.8	131.2	3.1:1
12 week	194	127	44	25.0	125.0	2.8:1
1 month after with*	-	-	-	-	-	-
3 month after with*	196	130	40	26	130	3.2:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal -

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment -

No change in STC, 4.2% \downarrow (STG),

No change in HDL, 0.92% \uparrow (LDL)

After 12 weeks of treatment -

3.1% \downarrow (STC), 9.3% \downarrow (STG),

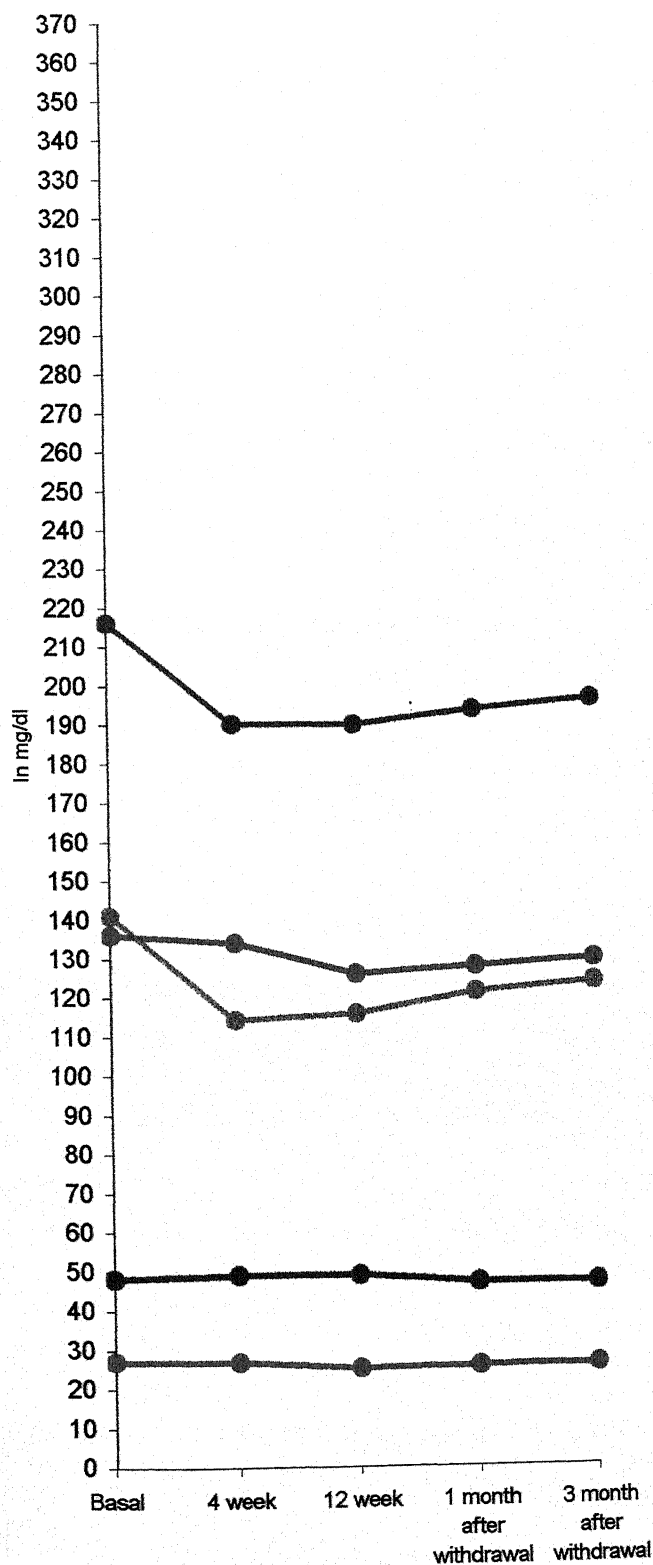
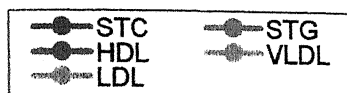
5% \uparrow (HDL), 3.8% \downarrow (LDL)

After 3 months of withdrawal -

2% \downarrow (STC), 7.1% \downarrow (STG),

5% \downarrow (HDL), No change in LDL

SIMVASTATIN GROUP



- Shiv dayal, 42 years/M
- Systemic hypertension
- Hypercholesterolemia

	In mg/dl					
	STC	STG	HDL	VLDL	LDL	LDL/HDL
Basal	216	136	48	27.0	141.0	2.9:1
4 week	190	134	49	26.8	114.2	2.3:1
12 week	190	126	49	25.2	115.8	2.4:1
1 month after with	194	128	47	25.6	121.4	2.6:1
3 month after with	197	130	47	26.0	124.0	2.6:1

STC 1 mmol/L = 38.76 mg/dl

STG mmol/L = mg/dl \times 0.0114

HDL mmol/L = mg/dl / 38.76

Fasting values :

Basal –

High STC, Normal STG,

Normal HDL and High LDL

After 4 weeks of treatment –

12.03% \downarrow (STC), 1.47% \downarrow (STG),

2.08% \uparrow (HDL), 19.0% \downarrow (LDL)

After 12 weeks of treatment –

12.03% \downarrow (STC), 7.4% \downarrow (STG),

2.08% \uparrow (HDL), 17.9% \downarrow (LDL)

After 3 months of withdrawal –

8.8% \downarrow (STC), 4.4% \downarrow (STG),

2.08% \downarrow (HDL), 12.05% \downarrow (LDL)

Discussion

DISCUSSION

This work was conducted in the department of Medicine, M.L.B. Medical College, Jhansi on patients suffering from systemic hypertension, Diabetes Mellitus, Ischemic Heart Disease, Myocardial Infarction or Nephrotic syndrome having hypercholesterolemia ($>200\text{mg/dl}$), hypertriglyceridemia ($>200\text{mg/dl}$) or both.

The Changes in Serum total cholesterol (STC) :

The values obtained were compared with the basal values.

Group A (Raw garlic group) :

The mean basal fasting values of the patients in this group was 223.2 ± 28.45 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 208.4 ± 27.08 , 197.8 ± 11.76 , 211.0 ± 17.52 respectively, while the percentage decrease from the mean basal values are 6.74%, 9.43% and 3.05% respectively.

Group B (Garlic pearls group) :

The mean basal fasting values of the patients in this group was 211.8 ± 21.48 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 201.1 ± 19.49 , 191 ± 15.50 , 201.3 ± 11.55 respectively while the percentage decrease from the

mean basal values are 4.99%, 7.74%, 3.02% respectively. Two subjects after 3 months of withdrawal have even showed an increase in STC from basal value i.e. average 4%.

Group C (Simvastatin Group) :

The mean basal fasting values of STC of the patients in this group was 208 ± 10.45 . The values after 4 and 12 weeks of treatment and after 3 month of withdrawal are 198 ± 9.8 , 184.6 ± 12.24 , 202.6 ± 21.11 respectively while the percentage decrease from mean basal values are 6.06% (In 2 subjects no change is observed), 11.21%, 6.96% (In 2 subjects values increase more than basal value by an average of 14.25%) respectively.

On statistical analysis we found that the serum cholesterol lowering effect of raw garlic and garlic pearls were statistically insignificant ($P > 0.05$ in both groups) but the cholesterol lowering effect of simvastatin was statistically very significant ($P < 0.001$) after 12 weeks of treatment. After 3 months of withdrawal cholesterol lowering effect in all the three groups was insignificant.

The Changes in Serum triglyceride (STG) :

Group A (Raw garlic group) :

The mean basal fasting values of STG of patients in this group was 180.6 ± 79.40 . The values after 4 and 12 weeks of treatment and

after 3 months of withdrawal are 171.5 ± 64.06 , 149.2 ± 59.52 , 161.2 ± 67.67 respectively while the percentage decrease from mean basal values are 10.05%, 20.58%, 10.86% respectively. Although 2 patients in this group showed an increase in STG levels by 10.15%, 2.0% and 10.7% respectively.

Group B (Garlic pearls group)

The mean basal fasting value of STG of patients in this group was 169.8 ± 47.71 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 156.3 ± 44.71 , 141.8 ± 33.83 , 162.3 ± 41.99 respectively while the percentage decrease from mean basal values are 9.91% (2 subjects showed no change), 18.31% and 14.33% respectively.

Group C (Simvastatin group) :

The mean basal fasting values of STG of patients in this group was 224.1 ± 88.66 while the value after 4 and 12 weeks of treatment and after 3 months of withdrawal are 196.1 ± 67.19 , 163.2 ± 40.10 , 158.4 ± 55.30 respectively, while the percentage decrease from the mean basal values are 10.46%, 21.88% and 18.47% respectively.

On statistical analysis lowering of STG by raw garlic ($P > 0.4$) garlic pearls ($P > 0.2$) and of simvastatin ($P > 0.05$) after 12 weeks of

treatment remain insignificant. After 3 months of withdrawal lowering effect of STG remain statistically insignificant.

The Changes in High density lipoprotein (HDL) :

Group A (Raw garlic group) :

The mean basal fasting value of HDL in this group was 43.7 ± 7.56 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 43.3 ± 7.47 , 41.7 ± 7.20 , 41.0 ± 10.22 respectively.

After 4 weeks - HDL was decreased by 2.07%. 3 subjects showed no change and one subject showed an increase by 3.8%.

After 12 weeks - HDL found to decrease by 2.15%, 2 subjects showed no change and 2 subjects showed 4.3% increase.

After 3 months of withdrawal - Subjects showed 2.15% decrease in HDL 3 subjects showed no change.

Group B (Garlic pearls group) :

The mean basal fasting value of subjects in this group was 43.6 ± 1.87 while after 4 and 12 weeks of treatment and 3 months of withdrawal are 44.5 ± 1.01 , 45 ± 1.73 , 44.2 ± 0.98 respectively.

After 4 weeks - Subjects showed 5.5% increase while 1 subject showed no change and 2 subjects showed fall by 4.4%.

After 12 weeks - Subjects showed increase by 6.62%, 2 subjects showed fall by 4.35%.

After 3 months of withdrawal - Subjects showed increase by 4.8%, 1 subject showed no change and 2 subjects showed decrease by 3.2%.

Group C (Simvastatin group) :

The mean basal fasting value of HDL of subjects in this group was 48.2 ± 6.17 , while after 4 and 12 weeks of treatment and after 3 months of withdrawal are 48.8 ± 6.66 , 50.4 ± 6.14 , 47.3 ± 5.38 respectively.

After 4 weeks - Subjects showed an increase by 3.29%, 3 subjects showed no change and a fall by 6.6% in 1 subject.

After 12 weeks - Subjects showed an increase by 5.28%. No change in one subject.

After 3 months of withdrawal - Subjects showed increase by 9.15%, 1 subject no change and in 4 subjects decrease by 3.78%.

On analysis changes in HDL are statistically insignificant in all the three groups, after 4 and 12 weeks of treatment and after 3 months of withdrawal.

The Changes in Very Low Density Lipoprotein (VLDL) :

Group A (Raw garlic group) :

The mean basal fasting value of VLDL in subjects of this group was 36.1 ± 15.82 , while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 34.3 ± 12.81 , 29.8 ± 11.98 , 32.2 ± 13.53 respectively.

Group B (Garlic Pearls group) :

The mean basal fasting values of the VLDL in subjects of this group was 33.8 ± 9.48 , while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 31.2 ± 8.98 , 28.4 ± 6.88 , 32.5 ± 7.10 respectively.

Group C (Simvastatin group) :

The mean basal fasting values of the VLDL in subjects of this group was 44.8 ± 17.72 , while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 39.2 ± 13.29 , 32.5 ± 8.00 , 31.7 ± 12.09 respectively.

On analysis the changes in VLDL i.e. the decrease in all the three groups are statistically insignificant, after 4 and 12 weeks of treatment and after 3 months of withdrawal.

The Changes in LDL (Low Density Lipoprotein) :

Group A (Raw Garlic group) :

The mean basal fasting value of LDL in subjects of this group was 143.3 ± 21.53 , while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 131.5 ± 18.13 , 126.4 ± 13.24 , 137.8 ± 18.35 respectively.

After 4 weeks subjects showed decrease by 8.75% except one subject who showed increase by 1.09%.

After 12 weeks subjects showed decrease by 15.87%, in 2 subjects increase by 0.445%.

After 3 months of withdrawal the fall remained to 6.13% and in 2 subjects an increase was noted by 4.0%

Group B (Garlic Pearls group)

The mean fasting value of LDL in this group was 134.4 ± 30.17 , while after 4 and 12 weeks of treatment and after 3 months of withdrawal are 125.4 ± 26.97 , 117.6 ± 21.87 , 124.6 ± 18.76 respectively.

After 4 weeks of treatment - Subjects showed a fall by 7.36%, in 1 subject an increase by 0.97% was noted.

After 12 weeks of treatment - Fall by 9.55%, in 1 subject an increase by 0.97% was noted.

After 3 months of withdrawal- Only 2 subjects showed a fall by 4.85%, rest of the subjects showed a rise by 6.65%.

Group C(Simvastatin group)

The mean basal fasting value of LDL of subjects in this group was 115.9 ± 19.99 , while after 4 weeks and 12 weeks of treatment and after 3 months of withdrawal are 109.8 ± 15.39 , 101.7 ± 17.28 , 123.6 ± 30.58 respectively.

After 4 weeks of treatment - LDL decreased by 11.29% in 5 subjects and 4.38% increase was noted in 4 subjects.

After 12 weeks of treatment - Decrease of 13.81% was noted, in 1 subject increase by 5.5% was noted.

After 3 months of withdrawal - LDL fall of 13.05% was noted, 1 subject showed no change and 3 subjects showed an average increase of 26.3%.

On statistical analysis the changes in LDL i.e. the lowering effect of LDL in all the three groups was statistically insignificant, after 4 and 12 weeks of treatment. Values remain insignificant after 3 months of withdrawal.

The present study does not substantiate the lipid lowering effect of raw garlic or garlic pearls as lowering of serum total cholesterol is statistically insignificant.

A study conducted by **Arora RC, Arora S et al (1981)** at the Department of Medicine, M.L.B. Medical College, Jhansi; substantiated the similar conclusion that the STC rise after fat intake was not prevented by intake of garlic. Their published data indicated that garlic had no effect of STC¹.

A similar study conducted by **Arora RC, Arora S, Gupta RK et al** at M.L.B. Medical College and Hospital, Jhansi i.e. "**The long term use of garlic in ischemic heart disease**" showed marginal fluctuation in STC after garlic pearls. Statistical analysis of their mean gave insignificant P values⁶.

The present study has shown that few subjects while on raw garlic revealed an increase of serum triglyceride instead of a fall.

We know that increase carbohydrate in diet lead to increase in plasma triglyceride levels. It may have been possible that when we tried to restrict subjects on routine diets not rich in fat and cholesterol some subjects may have increased carbohydrate in their diet hence result we found were inconsistent.

Secondly study conducted by **Arora RC, Arora S, Gupta RK, et al**⁶ showed in their published data the levels STG have risen twice during the period of garlic use from the mean basal values. statistical analysis were found to be insignificant which is similar to the present study.

Thirdly meta- analysis by **Neil, CA Silagy**³³ had shown that TG levels ranges from (1.24-2.10 mmol/L) at baseline to (0.94-2.34 mmol/L) after garlic therapy. Henceforth it reveals that STG had raised in few subjects.

Fourthly **Steiner, et al**³² had reported that there was a transient elevations in total cholesterol and triacylglycerol concentrations during initial supplementation this was later followed by a significant reduction below baseline levels.

In our study we found no statistically significant change in the level of HDL. Few subjects showed a decrease in HDL levels, while on raw garlic or garlic pearls.

A study showed that large intake of carbohydrates lead to increase in triglyceride levels and decrease in HDL levels. As Indians consume large carbohydrate diet and that would be the cause of fall of HDL level.

Meta-analysis of **Neil, CA Silagy**³³ had shown an insignificant rise of HDL, 1.14 ± 0.27 mmol/L to 1.21 ± 0.30 mmol/L, similar to the present study.

In present study LDL showed inconsistent results with statistically insignificant fall with increase in few subjects while on raw garlic or garlic pearls.

Similar results of increase in LDL level and insignificant P value was shown by **Arora RC, Arora S, Gupta RK et al.**

A large meta-analysis conducted by **Neil, CA Silagy, T Lancaster, J Hodgeman et al** published in the Journal of the Royal College of Physicians of London Vol 30, No-4, 1996 had shown that levels of LDL had increased after garlic therapy from 5.08 ± 0.56 o 5.14 ± 0.69 mmol/L.

As one subject in present study had shown a rise in LDL after 4 weeks and then a fall. **Steiner, et al**³² had reported that there was a transient elevation of STC, STG and the ratio of LDL to very low density lipoprotein followed by a fall while on garlic therapy.

Similar to the present study, **Leon A, Simon et al** concluded in his study that garlic powder tablets appeared to have no significant effect on lipid lipoprotein profile.

The present study concluded that the cholesterol lowering effect of simvastatin is very significant ($p < 0.001$) which is similar to the 4S study⁵⁰ conducted on simvastatin.

Lowering of STG by simvastatin is 21.88% in present study after 12 weeks of treatment which is within the range of drop of STG by statins in the report published by NCEP Adult treatment Panel-III⁶¹.

Increase in HDL by simvastatin was found to be 5.248% which is within the range of HDL increase by statins as published in the report of NCEP-Adult treatment Panel-III⁶¹. Fall shows by one subject has an explanation similar to the above as in raw garlic and garlic pearls group.

The drop in the LDL level was 13.8% after 12 weeks of simvastatin therapy lower than the drop shown by NCEP – Adult treatment Panel-III⁶¹ report and 4S⁵⁰ study group but most of the patients had achieved the goal of LDL $< 100\text{mg/dl}$. Remaining subjects could have achieved the goal with higher dose of simvastatin which had not been given to the subjects of the present study.

Fasting values of the three groups i.e. Raw garlic, Garlic pearls and simvastatin at basal, after 12 weeks of treatment and after 3 months of withdrawal are :

	Results (Mean \pm SD) in mg/dl								
	Raw Garlic Group			Garlic Pearls Group			Simvastatin Group		
	Basal	12 weeks	After 3 months of withdrawal	Basal	12 weeks	After 3 months of withdrawal	Basal	12 weeks	After 3 months of withdrawal
STC	223.2 \pm	197.8 \pm	211.0 \pm	211.8 \pm	191.0 \pm	201.3 \pm	208.0 \pm	184.6 \pm	202.6 \pm
	28.45	11.76	17.52	21.48	15.50	11.55	10.45	12.24	21.11
STG	180.6 \pm	149.2 \pm	161.2 \pm	169.8 \pm	141.8 \pm	162.3 \pm	224.1 \pm	163.2 \pm	158.4 \pm
	79.40	59.52	67.67	47.71	33.83	41.99	88.66	40.10	55.30
HDL	43.7 \pm	41.7 \pm	41.0 \pm	43.6 \pm	45.0 \pm	44.2 \pm	48.2 \pm	50.4 \pm	47.3 \pm
	7.56	7.20	10.22	1.87	1.73	0.98	6.7	6.14	5.38
VLDL	36.1 \pm	29.8 \pm	32.2 \pm	33.8 \pm	28.4 \pm	32.5 \pm	44.8 \pm	32.5 \pm	31.7 \pm
	15.82	11.98	13.53	9.48	6.88	7.10	17.72	8.00	12.09
LDL	143.3 \pm	126.4 \pm	137.8 \pm	134.4 \pm	117.6 \pm	124.6 \pm	115.9 \pm	101.7 \pm	123.6 \pm
	21.53	13.24	18.35	30.17	21.87	18.76	19.99	17.28	30.58

Summary & Conclusion

SUMMARY AND CONCLUSION

This study consisted of 27 subjects which were randomly being grouped into three groups, each group comprised of 9 subjects. Individuals who were hypercholesterolemic ($>200\text{mg/dl}$) or were having high serum triglyceride level ($>200\text{ mg/dl}$) or both were selected for the study. Individuals of group A were counselled to take one clove of raw garlic per day. Subjects of group B were counselled to take 4 garlic pearls (each capsule containing 0.625mg of garlic oil, i.e. garlic oil 0.25% w/w excipients qs to 250mg). Individuals of group C were counselled to take simvastatin 20mg per day.

Changes in serum total cholesterol in the simvastatin group was statistically very significant ($p<0.001$) after 12 weeks of treatment. No significant effect was found in the raw garlic and garlic pearls group although the levels decreased after 12 weeks of treatment.

No significant effect was found in the levels of STG, HDL and LDL in any of the group after 12 weeks of treatment.

After 3 months of withdrawal the values of STC, STG, LDL and HDL remain statistically insignificant in all the three groups.

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Master Charts

MASTER CHART

[Group A - Raw Garlic (STC)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Puttan	40/M	258	226	213	227	240
2	Premdubey	46/F	206	186	182	-	-
3	Ragvendra Sharma	68/M	200	186	-	-	192
4	Madan Mohan Soni	41/M	217	210	207	210	215
5	Raja Bai	52/F	213	200	-	-	-
6	Ram Rati	40/F	281	267	-	-	-
7	Lila Devi	60/F	212	198	191	200	210
8	Shanti Devi	65/F	202	194	190	196	198
9	Dinesh Kumar Gupta	43/M	220	-	204	-	-
Mean± SD		50.5± 10.6yrs	223.2 ±28.45	208.4 ±27.08	197.8 ±11.76	208.3 ±13.81	211.0 ±17.52

(Statistical analysis of STC)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	1.131	2.053	0.899
DF (degree of freedom)	15	13	12
P value	>0.2	>0.05	>0.3
Remark	Insignificant	Insignificant	Insignificant

[Group A - Raw Garlic (STG)]

Result in mg/dl							
S.No.	Name	Age/ Sex	1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Puttan	40/M	141	160	156	157	159
2	Premdubey	46/F	166	142	134	-	-
3	Ragvendra Sharma	60/M	123	118	-	-	121
4	Madan Mohan Soni	41/M	160	140	107	120	136
5	Raja Bai	52/F	162	160	-	-	-
6	Ram Rati	40/F	300	262	-	-	-
7	Lila Devi	60/F	103	110	107	109	112
8	Shanti Devi	65/F	331	280	265	270	278
9	Dinesh Kumar Gupta	43/M	140	-	126	-	-
Mean± SD		50.5± 10.6yrs	180.6± 79.40	171.5± 64.06	149.2± 59.52	164.0± 73.58	161.2± 67.67

(Statistical analysis of STG)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.257	0.823	0.459
DF (degree of freedom)	15	13	12
P value	>0.8	>0.4	>0.6
Remark	Insignificant	Insignificant	Insignificant

[Group A - Raw Garlic (HDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Puttan	40/M	46	45	45	44	45
2	Premdubey	46/F	42	42	44	-	-
3	Ragvendra Sharma	68/M	45	44	-	-	44
4	Madan Mohan Soni	41/M	45	45	45	45	45
5	Raja Bai	52/F	45	45	-	-	-
6	Ram Rati	40F	55	54	-	-	-
7	Lila Devi	60/F	45	44	44	44	45
8	Shanti Devi	65/F	26	27	27	26	26
9	Dinesh Kumar Gupta	43/M	45	-	45	-	-
Mean± SD		50.5± 10.6yrs	43.7± 7.56	43.3± 7.47	41.7± 7.20	39.8± 9.06	41.0± 10.22

(Statistical analysis of HDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.209	0.511	0.547
DF (degree of freedom)	15	13	12
P value	>0.8	>0.6	>0.5
Remark	Insignificant	Insignificant	Insignificant

[Group A - Raw Garlic (VLDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Puttan	40/M	28	32	31.2	31.4	31.8
2	Premdubey	46/F	33	28.4	26.8	-	-
3	Ragvendra Sharma	68/M	25	23.6	-	-	24.2
4	Madan Mohan Soni	41/M	32	28	21	24	27.2
5	Raja Bai	52/F	32	32	-	-	-
6	Ram Rati	40/F	60	52.4	-	-	-
7	Lila Devi	60/F	21	22	21.8	21.8	22.4
8	Shanti Devi	65/F	66.2	56	53	54	55.6
9	Dinesh Kumar Gupta	43/M	28	-	25.2	-	-
Mean± SD		50.5± 10.6yrs	36.1± 15.82	34.3 ± 12.81	29.8± 11.98	32.8 ± 14.71	32.2 ± 13.53

(Statistical analysis of VLDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.255	0.832	0.463
DF (degree of freedom)	15	13	12
P value	>0.8	>0.4	>0.6
Remark	Insignificant	Insignificant	Insignificant

[Group A - Raw Garlic (LDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Puttan	40/M	184	154	136.8	151.6	163.2
2	Premdubey	46/F	131	115.6	111.2	-	-
3	Ragvendra Sharma	68/M	130	118.4	-	-	123.8
4	Madan Mohan Soni	41/M	140	137	141	141	142.8
5	Raja Bai	52/F	136	123	-	-	-
6	Ram Rati	40/F	166	160.6	-	-	-
7	Lila Devi	60/F	146	132	125.6	134.2	142.6
8	Shanti Devi	65/F	109.8	111	110	116	116.4
9	Dinesh Kumar Gupta	43/M	147	-	133.8	-	-
Mean± SD		50.5± 10.6yrs	143.3± 21.53	131.5± 18.13	126.4± 13.24	135.7± 15.00	137.8± 18.35

(Statistical analysis of LDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	1.210	1.708	0.480
DF (degree of freedom)	15	13	12
P value	>0.2	>0.1	>0.6
Remark	Insignificant	Insignificant	Insignificant

[Group B -Garlic Pearls (STC)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	SA Kadri	42/M	188	186	181	185	186
2	M Barua	45/F	217	212	210	212	215
3	Sunil Kumar	35/M	200	188	182	187	211
4	Hanuman Prasad	66/M	200	190	-	-	-
5	Ashok Srivastava	39/M	205	181	176	180	190
6	Kamta Prasad	50/M	257	240	-	-	-
7	Chandra Shekar Diwedi	52/M	233	221	216	-	-
8	Ramgopal Kushwaha	50/M	195	192	186	190	200
9	Mr. Omar Mohammad	60/M	212	200	186	192	206
Mean± SD		48.7±	211.8±	201.1±	191.0±	191.0±	201.3±
		9.8yrs	21.48	19.49	15.50	11.09	11.55

(Statistical analysis of STC)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	1.11	2.101	1.088
DF (degree of freedom)	16	14	14
P value	>0.2	0.05	0.2
Remark	Insignificant	Insignificant	Insignificant

[Group B - Garlic Pearls (STG)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	SA Kadri	42/M	200	200	173	180	180
2	M Barua	45/F	152	117	107	110	117
3	Sunil Kumar	35/M	170	156	133	140	133
4	Hanuman Prasad	66/M	174	158	-	-	-
5	Ashok Srivastava	39/M	258	228	180	192	210
6	Kamta Prasad	50/M	117	117	-	-	-
7	Chandra Shekar Diwedi	52/M	100	98	98	-	-
8	Ramgopal Kushwaha	50/M	205	200	174	181	188
9	Mr. Omar Mohammad	60/M	153	133	128	132	146
Mean± SD		48.7±	169.8±	156.3±	141.8±	155.8±	162.3±
		9.8yrs	47.71	44.71	33.83	32.99	41.99

(Statistical analysis of STG)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.619	1.313	0.312
DF (degree of freedom)	16	14	13
P value	>0.5	>0.2	>0.7
Remark	Insignificant	Insignificant	Insignificant

[Group B - Garlic Pearls (HDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	SA Kadri	42/M	45	42	42	42	44
2	M Barua	45/F	40	45	45	45	44
3	Sunil Kumar	35//M	42	45	45	45	43
4	Hanuman Prasad	66/M	45	44	-	-	-
5	Ashok Srivastava	39/M	45	45	48	48	46
6	Kamta Prasad	50/M	43	45	-	-	-
7	Chandra Shekar Diwedi	52/M	43	45	45	-	-
8	Ramgopal Kushwaha	50/M	46	45	45	44	44
9	Mr. Omar Mohammad	60/M	44	45	45	45	44
Mean \pm SD		48.7 \pm 9.8yrs	43.6 \pm 1.87	44.5 \pm 1.01	45.0 \pm 1.73	44.8 \pm 1.94	44.2 \pm 0.98

(Statistical analysis of HDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	1.271	1.535	0.716
DF (degree of freedom)	16	14	13
P value	>0.2	>0.1	>0.4
Remark	Insignificant	Insignificant	Insignificant

[Group B - Garlic Pearls (VLDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	SA Kadri	42/M	40	40	35	36	36
2	M Barua	45/F	30	23.4	21	22	23.4
3	Sunil Kumar	35/M	34	31	27	28	27
4	Hanuman Prasad	66/M	35	31.6	-	-	-
5	Ashok Srivastava	39/M	51	45.6	36	38.4	42
6	Kamta Prasad	50/M	23	23	-	-	-
7	Chandra Shekar Diwedi	52/M	20	19.6	19.6	-	-
8	Ramgopal Kushwaha	50/M	41	40	34.8	36.2	37.6
9	Mr. Omar Mohammad	60/M	30.6	26.6	25.6	26.4	29.2
Mean± SD		48.7± 9.8yrs	33.8± 9.48	31.2± 8.98	28.4± 6.88	31.2± 6.6	32.5± 7.10

(Statistical analysis of VLDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.597	1.285	0.288
DF (degree of freedom)	16	14	13
P value	>0.5	>0.2	>0.7
Remark	Insignificant	Insignificant	Insignificant

[Group B - Garlic Pearls (LDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	SA Kadri	40/M	103	104	104	107	106
2	M Barua	45/F	147	143.6	144	145	147.6
3	Sunil Kumar	35/M	124	112	110	114	141
4	Hanuman Prasad	66/M	120	114.4	-	-	-
5	Ashok Srivastava	39/M	109	90.4	92	93.6	102
6	Kamta Prasad	50/M	191	172	-	-	-
7	Chandra Shekar Diwedi	52/M	170	156.4	151.4	-	-
8	Ramgopal Kushwaha	50/M	108	107	106.2	108.8	118.4
9	Mr. Omar Mohammad	60/M	137.4	128.4	115.4	120.6	132.8
Mean± SD		48.7±	134.4±	125.4±	117.6±	114.8±	124.6±
		9.8yrs	30.17	26.97	21.87	17.27	18.76

(Statistical analysis of LDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.667	1.449	0.705
DF (degree of freedom)	16	14	13
P value	>0.5	>0.1	>0.4
Remark	Insignificant	Insignificant	Insignificant

[Group C - Simvastatin (STC)]

Result in mg/dl							
S.No.	Name	Age/ Sex	1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Sunil Khattar	53/M	200	194	162	164	176
2	Laxmi Bai	60/F	200	196	176	200	240
3	Prabhudayal Yadav	40/M	228	212	188	-	-
4	Santosh Jain	42/M	217	210	200	202	206
5	Meera Bai	36/F	211	200	186	-	-
6	Harnarayan	50/M	200	180	172	183	186
7	D.C. Puneet	68/M	200	200	194	200	217
8	K.V. Nayak	44/M	200	200	194	-	196
9	Shivdayal	42/M	216	190	190	194	197
Mean± SD		48.3±	208.0±	198.0±	184.6±	190.5±	202.6±
		10.4yrs	10.45	9.8	12.24	14.72	21.11

(Statistical analysis of STC)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	2.082	4.365	0.673
DF (degree of freedom)	16	16	14
P value	>0.05	<0.001	>0.5
Remark	Insignificant	Very significant	Insignificant

[Group C - Simvastatin (STG)]

Result in mg/dl							
S.No.	Name	Age/ Sex	1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Sunil Khattar	53/M	360	288	184	210	270
2	Laxmi Bai	60/F	132	120	122	120	120
3	Prabhudayal Yadav	40/M	280	275	240	-	-
4	Santosh Jain	42/M	272	218	190	196	212
5	Meera Bai	36/F	320	260	187	-	-
6	Harnarayan	50/M	144	138	133	133	140
7	D.C. Puneet	68/M	233	198	160	140	107
8	K.V. Nayak	44/M	140	134	127	-	130
9	Shivdayal	42/M	136	134	126	128	130
Mean± SD		48.3±	224.1±	196.1±	163.2±	154.5±	158.4±
		10.4yrs	88.66	67.19	40.10	42.09	55.30

(Statistical analysis of STG)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.751	1.877	1.680
DF (degree of freedom)	16	16	14
P value	>0.4	>0.05	>0.1
Remark	Insignificant	Insignificant	Insignificant

[Group C - Simvastatin (HDL)]

S.No.	Name	Result in mg/dl					
		Age/ Sex	1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Sunil Khattar	53/M	52	55	57	55	55
2	Laxmi Bai	60/F	55	55	55	55	54
3	Prabhudayal Yadav	40/M	45	42	48	-	-
4	Santosh Jain	42/M	48	49	50	45	45
5	Meera Bai	36/F	59	60	61	-	-
6	Harnarayan	50/M	40	42	42	45	45
7	D.C. Puneet	68/M	45	45	48	45	45
8	K.V. Nayak	44/M	42	42	44	-	40
9	Shivdayal	42/M	48	49	49	47	47
Mean± SD		48.3± 10.4yrs	48.2± 6.7	48.8± 6.66	50.4± 6.14	48.6± 4.99	47.3± 5.38

(Statistical analysis of HDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.198	0.758	0.307
DF (degree of freedom)	16	16	14
P value	>0.8	>0.4	>0.7
Remark	Insignificant	Insignificant	Insignificant

[Group C - Simvastatin (VLDL)]

S.No.	Name	Age/ Sex	Result in mg/dl				
			1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Sunil Khattar	53/M	72	57	36	42	54
2	Laxmi Bai	60/F	26.4	24	24.4	24	24
3	Prabhudayal Yadav	40/M	56	55	48	-	-
4	Santosh Jain	42/M	54	43.6	38	39.2	43
5	Meera Bai	36/F	64	52	37.4	-	-
6	Harnarayan	50/M	29	28	27	27	28
7	D.C. Puneet	68/M	47	39.6	32	28	21.0
8	K.V. Nayak	44/M	28	26.8	25	-	26
9	Shivdayal	42/M	27	26.8	25.2	25.6	26
Mean± SD		48.3± 10.4yrs	44.8± 17.72	39.2± 13.29	32.5± 8.00	30.9± 7.63	31.7± 12.09

(Statistical analysis of VLDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.767	1.901	1.673
DF (degree of freedom)	16	16	14
P value	>0.4	>0.05	>0.1
Remark	Insignificant	Insignificant	Insignificant

[Group C - Simvastatin (LDL)]

S.No.	Name	Result in mg/dl					
		Age/ Sex	1 (Basal) At Regis.	2 4 week	3 12 week	4 1 month after withdrawal	5 3 month after with- drawal
1	Sunil Khattar	53/M	76	82	69	67	67
2	Laxmi Bai	60/F	118.6	117	96.6	121	162
3	Prabhudayal Yadav	40/M	127	115	92	-	-
4	Santosh Jain	42/M	115	117.4	112	117.8	118
5	Meera Bai	36/F	97	88	87.6	-	-
6	Harnarayan	50/M	131	108	103	110	113
7	D.C. Puneet	68/M	108	115.4	114	127	151.0
8	K.V. Nayak	44/M	130	131.2	125	-	130
9	Shivdayal	42/M	141	114.2	115.8	121.4	124
Mean± SD		48.3± 10.4yrs	115.9± 19.99	109.8± 15.39	101.7± 17.28	110.7± 22.12	123.6± 30.58

(Statistical analysis of LDL)

	Between I & II (Basal & After 4wks of treatment)	Between I & III (Basal & After 12wks of treatment)	Between I & V (Basal & After 3 months of withdrawal)
't' value	0.725	1.611	0.609
DF (degree of freedom)	16	16	14
P value	>0.4	>0.1	>0.5
Remark	Insignificant	Insignificant	Insignificant